

Table 1a. Study characteristics and descriptive results of STUDIES WITH A BROADER CONCEPT OF 'ADVERSE DRUG EVENTS', 'WITH INTENSIVE MONITORING'

Studies; End of data collection [year]; Country (SDI)	General information on the study design			Study population: Inclusion criteria			Methods of data collection			Descriptive outcomes on the paediatric patients	
	Setting 1) <i>Inpatient hospital departments</i> 2) <i>Emergency departments</i> (multicentre if applicable)	Temporal perspective: 1) <i>Prospective during clinical treatment</i> 2) <i>Retrospective (chart review)</i> 3) <i>Retrospective (database); Study period [months]</i>	Definition of 'drug-related problems'	Selection by ...			Methods of ...			a) Total number of evaluated paediatric admissions or visits b) Age of the total paediatric study population [years] c) Gender % male	Information on clinical characteristics a) Length of hospital stay (LOS) [days] b) Number of medications per admissions c) Main drug (classes) used (in more than 10% of admissions)
Buajordet 2002 ¹ ; [1996]; Norway (0.837)	1) General paediatric wards	1) Prospective; [5 months]	ADE, defined by study author	Exclusion: Patients of the neonatal unit	a) NR; b) NR; c) Explicitly included	≤ 15 years (neonates excluded)	Intensively monitored + spontaneous reporting	Naranjo algorithm ⁵⁶ ; 2) ≥ possible / likely	NA	a) 919 b) Mean age (range): 2.7 (0 - 16) c) 55%	a) NR b) NR c) Paracetamol (53%), Salbutamol (50%), Racemic adrenaline (42%), Phenoxymethylpenicillin (19%), Ampicillin (17%), Diazepam (13%), Thiopentone (12%), Amoxicillin (117%), Midazolam (11%), Nasal decongestants (11%)
Easton-Carter 2003 ² ; [1999]; Australia (0.774)	2) Paediatric emergency departments (3 centres)	1) Prospective; [4.2 months]	ADE, (Strand et al ⁴⁷)	Exclusions: Oncology + trauma / surgical patients	a) via ED; b) NR; c) NR	≤ 17 years	Intensively monitored	Expert judgement, see Dartnell et al ⁵⁸ ; 2) ≥ possible / likely	NA	a) 8 601 b) Mean age (SD): 4.1 (2) median: 2.0 c) 56.8%	a) NR b) NR c) NR
Easton 2004 ³ ; [1999]; Australia (0.774)	1) Paediatric wards (2 centres)	1) Prospective; [5.1 months]	ADE, (Strand et al ⁴⁷)	Exclusions: Oncology + trauma / surgical patients	a) Acutely admitted; b) NR; c) NR	≤ 17 years	Intensively monitored	Expert judgement, see Dartnell et al ⁵⁸ ; 2) ≥ possible / likely	Algorithm (according Schumock et al ⁶⁴)	a) 2 933 b) NR c) NR	a) NR b) Week prior to admission: Mean: 2 drugs; median 2.0 drugs, ± SD 1.4) c) NR
Sikdar 2010 ⁴ ^a ; [2007]; Canada (0.843)	2) Paediatric emergency department	2) Retrospective; [12 months]	ADE, (Nebeker et al ⁴⁸)	Exclusions: Trauma / surgical patients + admitted due to alcohol or drug abuse, a suicide attempt	a) via ED; b) NR; c) Explicitly included	≤ 17 years	Screening / trigger tool - subsequently: Intensively monitored	Expert judgement, criteria defined by study authors; 2) ≥ possible / likely	NA	a) 65 864 b) Mean age (SD): 6.8 (5.3) c) 51.2%	a) NR b) NR c) NR
Zed 2015 ⁵ ; [2012]; Canada (0.856)	2) Paediatric emergency department	1) Prospective; [12 months]	ADE, (Hepler and Strand ⁴⁹)	NR	a) via ED; b) NR; c) Explicitly included	≤ 18 years	Intensively monitored	Naranjo algorithm ⁵⁶ + WHO classification ⁵⁷ ; 1) ≥ probable / certain	NA	a) 2 028 b) Mean age (SD): 6.1 (5.0) c) 52.6%	a) Median LOS (IQR): 2.0 b) Mean: 1.1 drugs (1.3 SD) c) NR
Kang 2022 ⁶ ; [2014]; Korea (0.859)	1) Emergency departments (3 centres)	3) Retrospective (database: "NEDIS"); [6 months]	ADE, defined by study author	Exclusions: Patients with intentional overdose, drug abuse, and/or suicidal attempts	a) via ED; b) NR; c) NR	≤ 17 years	Screening - subsequently: Intensively monitored	Expert judgement (WHO classification ⁵⁷); 2) ≥ possible / likely	NA	a) 13 312 b) NR c) NR	a) NR b) NR c) NR
Toni 2019 ⁷ ^b ; [≤ 2019]; Germany (0.898)	1) General paediatric ward	1) Prospective; [10 months]	'ADR + ME'	NR	a) NR; b) min 24h; c) NR	≤ 17 years	Intensively monitored	NR; "detected medication error"	NR	a) 741 b) Median age (IQR): 7 (1 - 13) c) NR	a) Median LOS (IQR) = 2 (2 - 4) b) NR c) NR
Neubert 2023 ⁸ ; [2020]; Germany (0.898)	1) Paediatric wards (12 centres)	1) Prospective; [24 months]	ADE, (Möller and Aly ⁵⁰)	Exclusions: Oncology patients	a) Acutely admitted; b) NR; c) NR	≤ 17 years	Trigger tool - subsequently: Intensively monitored	Expert judgement (WHO classification ⁵⁷) + consensus of 2 judgements; 2) ≥ possible / likely	NA	a) 2 497 b) NR c) NR	a) NR b) NR c) NR

Table 1b. Study characteristics and descriptive results of STUDIES WITH A BROADER CONCEPT OF ‘ADVERSE DRUG EVENTS’, ‘BASED ON ROUTINE MONITORING’

Studies; End of data collection [year]; Country (SDI)	General information on the study design			Study population: Inclusion criteria			Methods of data collection			Descriptive outcomes on the paediatric patients	
	Setting 1) <i>Inpatient hospital departments</i> 2) <i>Emergency departments</i> (multicentre if applicable)	Temporal perspective: 1) <i>Prospective during clinical treatment</i> 2) <i>Retrospective (chart review)</i> 3) <i>Retrospective (database); Study period [months]</i>	Definition of ‘drug-related problems’	Selection by ... clinical condition	admissions a) Circumstances of admission ○ <i>Admission via ED</i> ○ <i>Only acutely admitted inpatients;</i> b) Minimum duration of stay; c) Repeated ad-missions: Explicitly ○ <i>Included</i> ○ <i>Excluded</i>	age or defined age categories	Methods of ... monitoring DRP: <i>Intensively monitored (chart review / assessment) by study staff vs. routinely monitored (origin of collected data from routine healthcare processes (→ patient charts / discharge diagnosis / E-codes))</i>	causality assessment (between drug and problem) Level of causality 1) ≥ <i>probable / certain</i> 2) ≥ <i>possible / likely</i> 3) ≥ <i>conditional / doubtful</i> 4) <i>else</i>	prevent-ability assessment	a) Total number of evaluated paediatric admissions or visits b) Age of the total paediatric study population [years] c) Gender % male	Information on clinical characteristics a) Length of hospital stay (LOS) [days] b) Number of medications per admissions c) Main drug (classes) used (in more than 10% of admissions)
Temple 2004 ^a ; [1999]; US (0.794)	1) Inpatient hospital departments	3) Retrospective (database “hospital’s surveillance programme”); [72 months]	ADR + (un-) intentional overdosage (including prescribing errors)	NR	a) NR; b) NR; c) NR	‘Paediatric’	Voluntary ADR report/ routinely detected by quality improvement staff/ hospital pharmacy (medical records, discharge coding); subsequently chart review	Naranjo algorithm ⁵⁶ ; 2) ≥ possible / likely	NA	a) 65 864 b) NR c) NR	a) NR b) NR c) NR
Bourgeois 2009 ^{10 a} ; [2005]; US (0.812)	2) Emergency departments and outpatient clinics (multicentre)	3) Retrospective (database: “NAMCS” and “NHAMCS”); [132 months]	ADE, (Bates et al ⁵¹)	NR	a) via ED; b) NR; c) NR	≤ 17 years	Routine diagnostic in clinical practice	NR	NA	a) NR b) NR c) NR	a) NR b) NR c) NR
Cohen 2008 ^{11 a} ; [2005]; US (0.812)	2) Emergency departments (multicentre)	3) Retrospective (database: “NEISS-CADES”); [24 months]	ADE, defined by study author	NR	a) via ED; b) NR; c) NR	≤ 18 years	Identification and classification using routine data	NR	NA	a) NR b) NR c) NR	a) NR b) NR c) NR
Tundia 2011 ¹² ; [2006]; US (0.811)	1) Inpatient hospital departments (multicentre)	3) Retrospective (database: “2006 KID”); [12 months]	ADE, (Elixhauser et al ⁵²)	NR	a) NR; b) NR; c) NR	≤ 20 years	Routine diagnostic in clinical practice	NR	NA	a) 7 558 812 b) Mean age (SE): 4.6 (0.04) c) 46.8%	a) Mean LOS: 3.7 b) NR c) NR
Feinstein 2014 ¹³ ; [2010]; US (0.832)	2) Emergency departments (multicentre)	3) Retrospective (database: “National Emergency Department Sample”); [60 months]	“ADE, without wrong substance administration, poisoning, intentional self-harm, or use of illicit substances”	Exclusion: Oncology patients	a) via ED; b) NR; c) Explicitly excluded	≤ 17 years	Routine diagnostic in clinical practice	NR	NA	a) NR b) Median age 5 - 9 years (age categories distribution: <1 (12.1%), 1 - 4 (29.0%), 5 - 9 (18.5%), 10 - 18 (40.4%)) c) 51.8%	a) NR b) NR c) NR
Romano-Lieber 2011 ^{14 b} ; [≤ 2011]; Brazil (0.597)	2) Paediatric emergency department	2) Retrospective; [NR]	ADE, defined by study author	NR	a) via ED; b) NR; c) NR	‘Paediatric’	Routine diagnostic in clinical practice	NR	NA	a) 23 286 b) NR c) NR	a) NR b) NR c) NR
Silva 2017 ¹⁶ ; [2014]; Brazil (0.616)	1) Inpatient hospital departments (Paediatrics as subgroup) (multicentre)	3) Retrospective (database: “Hospital Information System database, DATASUS”); [36 months]	ADE, defined by study author	NR	a) NR; b) NR; c) NR	≤ 19 years	Routine diagnostic in clinical practice	NR	NA	a) 706 092 b) NR c) NR	a) NR b) NR c) NR
Rosafio 2017 ¹⁵ ; [2014]; Italy (0.789)	2) Emergency department	2) Retrospective; [96 months]	ADE, (Hepler and Strand ⁴⁹)	NR	a) via ED; b) NR; c) NR	≤ 13 years	Identification and classification using routine data	Naranjo algorithm ⁵⁶ + WHO classification ⁵⁷ ; 1) ≥ probable / certain	NA	a) 147 643 b) NR c) NR	a) NR b) NR c) NR

Table 1c. Study characteristics and descriptive results of STUDIES WITH A NARROWER CONCEPT OF ‘ADVERSE DRUG REACTIONS’, ‘WITH INTENSIVE MONITORING’

Studies; End of data collection [year]; Country (SDI)	General information on the study design			Study population: Inclusion criteria			Methods of data collection			Descriptive outcomes on the paediatric patients	
	Setting 1) <i>Inpatient hospital departments</i> 2) <i>Emergency departments</i> (multicentre if applicable)	Temporal perspective: 1) <i>Prospective during clinical treatment</i> 2) <i>Retrospective (chart review)</i> 3) <i>Retrospective (database); Study period [months]</i>	Definition of ‘drug-related problems’	Selection by ... clinical condition	admissions a) Circumstances of admission o <i>Admission via ED</i> o <i>Only acutely admitted inpatients;</i> b) Minimum duration of stay; c) Repeated ad-missions: Explicitly o <i>Included</i> o <i>Excluded</i>	age or defined age categories	Methods of ... monitoring DRP: <i>Intensively monitored (chart review / assessment) by study staff vs. routinely monitored (origin of collected data from routine healthcare processes (→ patient charts / discharge diagnosis / E-codes))</i>	causality assessment (between drug and problem) Level of causality 1) <i>≥ probable / certain</i> 2) <i>≥ possible / likely</i> 3) <i>≥ conditional / doubtful</i> 4) <i>else</i>	prevent-ability assessment	a) Total number of evaluated paediatric admissions or visits b) Age of the total paediatric study population [years] c) Gender % male	Information on clinical characteristics a) Length of hospital stay (LOS) [days] b) Number of medications per admissions c) Main drug (classes) used (in more than 10% of admissions)
Pouyanne 2000 ¹⁷ ; [1998]; France (0.773)	1) Inpatient hospital departments (Paediatrics as subgroup) (multicentre)	1) Prospective; [0.5 months]	ADR, WHO definition ⁵³	NR	a) NR; b) NR; c) NR	≤ 15 years	Intensively monitored	NR	NA	a) 525 b) NR c) NR	a) NR b) NR c) NR
Jonville-Béra 2002 ¹⁸ ; [1998]; France (0.773)	1) Various inpatient paediatric hospital departments	1) Prospective; [0.2 months]	‘ADR’	Exclusion: Accident and emergency department patients	a) NR; b) min 24h; c) NR	‘Paediatric’	Intensively monitored	Algorithm, see Bégaud et al ⁵⁹ ; "suspected relationship"	NA	a) 260 b) Mean age (SD): 6.3 (5.1) c) 60.4%	a) Median LOS (range): 3 (1 - 70) b) Before admission: Median: 2 drugs (range 1 – 11) During admission: Median: 3 drugs (range 1 – 14) c) NR
Haffner 2005 ¹⁹ ; [2001]; Germany (0.853)	1) General paediatric wards, PICU	1) Prospective; [1.5 months]	ADR, WHO definition ⁵³	Exclusion: Oncology patients Inclusion: General ward + ICU patients	a) NR; b) NR; c) Explicitly included	‘Paediatric’	Two methods: 1) Intensively monitored (incl. interviews) 2) Trigger tool + subsequently intensive assessment	Expert judgement, WHO classification ⁵⁷ ; 2) <i>≥ possible / likely</i>	NA	a) 411 b) No pooled data Cohort 1: Mean age (SD): 4.6 (5.1) Median age: 2.2 Cohort 2: Mean age (SD): 5.0 (5.3) Median age 2.4 c) 58.9%	a) No pooled data Cohort 1: Mean LOS (SD): 7.2 (13.2) Median LOS: 5 Cohort 2: Mean LOS (SD): 7.0 (13.6) Median LOS 4.0 b) NR c) NR
Weiss 2002 ²⁰ ; [≤ 2002]; Germany (0.856)	1) Paediatric infectious diseases department	1) Prospective; [8 months]	ADR, WHO definition ⁵³	Inclusion: Patients admitted to paediatric isolation ward	a) NR; b) NR; c) NR	‘Paediatric’	Computerised automatically generated laboratory signals + Intensively monitored	Algorithm, see Evans et al ⁶⁰ = adapted Naranjo algorithm ⁵⁶ ; 2) <i>≥ possible / likely</i>	NA	a) 214 b) Median age (range): 8.6 (0.1 - 35) c) NR	a) Median LOS (range): 6.9 (1 - 187) b) NR c) NR
Lamabadusuriya 2003 ²¹ ; [2002]; Sri Lanka (0.582)	1) All medical inpatient hospital departments	1) Prospective; [11 months]	ADR, WHO definition ⁵³	Inclusion: Medical ward patients	a) NR; b) NR; c) NR	‘Paediatric’	Intensively monitored	Naranjo algorithm ⁵⁶ ; 2) <i>≥ possible / likely</i>	NA	a) 39 625 b) NR c) NR	a) NR b) NR c) NR
Fattahi 2005 ²² ; [2004]; Iran (0.562)	1) Paediatric department of Infectious Diseases	1) Prospective; [5 months]	ADR, WHO definition ⁵³	Inclusion: Infectious diseases department patients	a) NR; b) min 24h; c) Explicitly excluded	≤ 14 years	Intensively monitored	Expert judgement (WHO classification ⁵⁷); 3) <i>≥ conditional / doubtful</i>	NA	a) 404 b) NR c) NR	a) Mean LOS: 6.5 (2611 patient-days / 404 patients) b) Mean: 3.4 drugs (SD 2.95; range: 0 – 20) c) NR
Oshikoya 2007 ²³ b; [2006]; Nigeria (0.402)	1) Inpatient department for paediatric medical conditions	2) Retrospective; 30 months] + 1) Prospective; [6 months]	‘ADR’	Inclusion: Various forms of paediatric medical conditions	a) NR; b) NR; c) NR	‘Paediatric’	Two datasets: 1) Routine diagnostic in clinical practice 2) Intensively monitored	NR	NA	a) 3 821 b) NR c) NR	a) NR b) NR c) NR
Bénard-Larivière 2015 ²⁴ ; [2007]; France (0.799)	1) Inpatient medical wards (Paediatrics as subgroup) (multicentre)	1) Prospective; [0.5 months]	ADR, WHO definition ⁵³	NR	a) NR; b) min 24h; c) NR	≤ 15 years	Intensively monitored	Expert judgement: criteria defined by study authors; <i>≥ ‘possible’</i> , according to the study authors (not formally hierarchical)	NA	a) 518 b) NR c) NR	a) NR b) NR c) NR
Oshikoya 2011 ²⁵ ; [2007]; Nigeria (0.412)	1) Inpatient department for paediatric medical conditions	1) Prospective; [18 months]	ADR, (Edwards and Aronson ⁵³)	NR	a) NR; b) min 24h; c) Explicitly excluded	‘Paediatric’	Trigger tool + Intensively monitored	Algorithm, see Jones et al ⁶¹ ; 2) <i>≥ possible / likely</i>	NA	a) 2 004 b) NR c) 61.0%	a) NR b) Mean: 4.2 drugs (range 2 – 10) c) NR

Table 1c. Study characteristics and descriptive results of STUDIES WITH A NARROWER CONCEPT OF ‘ADVERSE DRUG REACTIONS’, ‘WITH INTENSIVE MONITORING’

Studies; End of data collection [year]; Country (SDI)	General information on the study design			Study population: Inclusion criteria			Methods of data collection			Descriptive outcomes on the paediatric patients	
	Setting 1) <i>Inpatient hospital departments</i> 2) <i>Emergency departments</i> (multicentre if applicable)	Temporal perspective: 1) <i>Prospective during clinical treatment</i> 2) <i>Retrospective (chart review)</i> 3) <i>Retrospective (database); Study period [months]</i>	Definition of ‘drug-related problems’	Selection by ... clinical condition	admissions a) Circumstances of admission o <i>Admission via ED</i> o <i>Only acutely admitted inpatients;</i> b) Minimum duration of stay; c) Repeated ad-missions: Explicitly o <i>Included</i> o <i>Excluded</i>	age or defined age categories	Methods of ... monitoring DRP: <i>Intensively monitored (chart review / assessment) by study staff vs. routinely monitored (origin of collected data from routine healthcare processes (→ patient charts / discharge diagnosis / E-codes))</i>	causality assessment (between drug and problem) Level of causality 1) ≥ <i>probable / certain</i> 2) ≥ <i>possible / likely</i> 3) ≥ <i>conditional / doubtful</i> 4) <i>else</i>	prevent-ability assessment	a) Total number of evaluated paediatric admissions or visits b) Age of the total paediatric study population [years] c) Gender % male	Information on clinical characteristics a) Length of hospital stay (LOS) [days] b) Number of medications per admissions c) Main drug (classes) used (in more than 10% of admissions)
Gallagher 2011 ²⁶ ; [2008]; UK (0.811)	1) Paediatric main hospital wards, observation ward	1) Prospective; [0.5 months]	ADR, (Edwards and Aronson ⁵³)	Exclusion: Patients with accidental or intentional overdose	a) Acutely admitted; b) Subgroup: main ward: min 4h; observation ward: max 4h; c) Explicitly included	‘Paediatric’	Intensively monitored	Naranjo algorithm ⁵⁶ ; 2) ≥ possible / likely	Definition (Hallas et al ⁶⁵)	a) 822 b) NR c) NR	a) NR b) NR c) NR
Posthumus 2012 ²⁷ ; [2008]; The Netherlands (0.856)	2) Emergency departments and outpatient clinics, admitting patients to paediatric wards and ICU	1) Prospective; [5 months]	ADR, (Krähenbühl-Melcher et al ⁵⁴)	Exclusion: Patients admitted due to alcohol or drug abuse, a suicide attempt	a) via ED; b) NR; c) Explicitly included	≤ 18 years	Trigger tool + Intensively monitored	Naranjo algorithm ⁵⁶ ; 2) ≥ possible / likely	Algorithm (Schumock et al ⁶⁴)	a) 683 b) Median age (range): 3.2 (0 - 17.9) c) 59.0%	a) NR b) NR c) Main drug classes: drugs for the alimentary tract and metabolism, the nervous system, and anti-infectives for systemic use
Gallagher 2012 ²⁹ / Bellis 2014 ²⁸ ; [2009]; UK (0.813)	1) Paediatric main hospital wards (general and specialty care)	1) Prospective; [12 months]	ADR, (Edwards and Aronson ⁵³)	Exclusion: Patients with accidental or intentional overdose, misuse of medicines, elective admissions	a) Acutely admitted; b) min 4h (main ward patients, exclusion of observation ward patients) c) Explicitly included	‘Paediatric’	Intensively monitored	Algorithm, see Liverpool ADR Causality Assessment Tool, Gallagher et al ⁶² ; 2) ≥ possible / likely	Definition (Hallas et al ⁶⁵)	a) 8 345 b) Median age (IQR): 3.1 (0.8 - 9) (calculated for patients exposed to any medication in the 2 weeks prior hospitalisation on their first admission) c) 58.0%	a) NR b) Median 2 drugs (IQR: 1; 3) (calculated for patients exposed to any medication in the 2 weeks prior hospitalisation) c) NR
Langerová 2014 ³⁰ ; [2012]; Czech Republic (0.818)	1) Inpatient department of paediatrics	1) Prospective; [9 months]	ADR, (Edwards and Aronson ⁵³)	NR	a) NR; b) NR; c) Explicitly included	≤ 19 years	Intensively monitored	Naranjo algorithm ⁵⁶ + Liverpool ADR Causality Assessment Tool ⁶² + Edwards and Aronson ⁵³ causality assessment method; 2) ≥ possible / likely	NA	a) 2 903 b) Mean age (SD): 7.1 (5.7) c) 57.3%	a) NR b) NR c) NR
Russom 2017 ³¹ *; [2014]; Eritrea (0.360)	1) Eritrean inpatient hospital departments (Paediatrics as subgroup) (multicentre)	1) Prospective; [5 months]	ADR, WHO definition ⁵³	Exclusion: Neonates, mothers admitted for delivery reasons	a) NR; b) NR; c) NR	≤ 15 years (neonates excluded)	Intensively monitored	Naranjo algorithm ⁵⁶ ; 2) ≥ possible / likely	NA	a) 2 433 b) NR c) NR	a) NR b) NR c) NR
Gholami 2015 ³² ; [2015]; Iran (0.649)	2) Paediatric emergency department	1) Prospective; [6 months]	ADR, (Edwards and Aronson ⁵³)	Exclusion: Patients with overdoses, suicide attempt, medication error	a) via ED; b) min 6h; c) NR	≤ 18 years	Intensively monitored	Naranjo algorithm ⁵⁶ + Expert judgement (WHO classification ⁵⁷); 2) ≥ possible / likely	Algorithm (Schumock et al ⁶⁴)	a) 658 b) Mean age (SD): 3.4 (3) c) NR	a) NR b) NR c) NR
Mouton 2020 ³³ ; [2015]; South Africa (0.664)	1) general and specialist medical, wards, high-care, intensive care unit + medical wards, high-care, intensive care unit (2 centres)	1) Prospective; [1 month] + 2) Retrospective; [1 month]	ADR, (Aronson and Ferner ⁵⁵)	Exclusion: Patients of surgical and oncology wards, limited neonatal service Inclusion: Various wards + ICU patients	a) Subgroup of acutely admitted patients; b) NR c) Explicitly included	≤ 18 years	Trigger tool + Intensively monitored	Expert judgement (WHO classification ⁵⁷); 2) ≥ possible / likely	Algorithm (Schumock et al ⁶⁴)	a) 1 106 b) Median age (IQR): 0.9 (0.1 - 3.4) c) 56.0%	a) Median LOS (IQR) = 3 (2 - 6) (range: 1 - 34 days); 2) b) Before admission: Median: 2 drugs (IQR 1 - 4, range 0 – 47) During admission: Median: 4 drugs (IQR 3 - 9, range 0 – 46) c) Beta-adrenergic inhalants (25.41%), antipyretics (25.05%), penicillins (19.08%), other beta-lactam antibiotics (13.74%), other drugs for obstructive airway disease (11.30%)

Studies; End of data collection [year]; Country (SDI)	General information on the study design			Study population: Inclusion criteria			Methods of data collection			Descriptive outcomes on the paediatric patients	
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Nasso 2020 ³⁴ ; [2018]; Italy (0.798)	2) Paediatric Emergency Department	1) Prospective; [84 months]	ADR, WHO definition ⁵³	NR	a) via ED; b) NR; c) NR	≤ 15 years	Intensively monitored	Naranjo algorithm ⁵⁶ ; 2) ≥ possible / likely	Algorithm (Schumock et al ⁶⁴)	a) 75 935 b) NR c) NR	a) NR b) NR c) NR
Patel 2021 ³⁵ ; [≤ 2021]; India (0.609)	1) Paediatric wards	1) Prospective; [22 months]	ADR, WHO definition ⁵³	NR	a) NR; b) NR; c) NR	≤ 12 years	Intensively monitored	Naranjo algorithm ⁵⁶ + Expert judgement (WHO classification ⁵⁷); 2) ≥ possible / likely	NA	a) 700 b) age distribution: 0y - 3y: 57.0%, 4y - 6y: 18.4%, 7y - 9y: 13.9%, 10y - 12y: 10.7% c) 56.9%	a) NR b) NR c) NR
Gupta 2023 ³⁶ ; [2013]; India (0.566)	1) Paediatric ward + paediatric intensive care unit	1) Prospective; [12 months]	ADR, (Edwards and Aronson ⁵³)	Exclusion: Patients with intentional or accidental poisoning, medication errors, and drug abuse Inclusion: Paediatric ward + ICU patients (without neonates, surgical patients)	a) NR; b) NR; c) NR	≤ 12 years (neonates excluded)	Intensively monitored	Expert judgement (WHO classification ⁵⁷); 1) ≥ probable / certain	NA	a) 6 026 b) age distribution: 1m - 1y: 24.8%, 1y - 5y: 36.1%, >5y: 39.0% c) NR	a) NR b) NR c) NR

Studies; End of data collection [year]; Country (SDI)	General information on the study design			Study population: Inclusion criteria			Methods of data collection			Descriptive outcomes on the paediatric patients	
	Setting 1) <i>Inpatient hospital departments</i> 2) <i>Emergency departments</i> (multicentre if applicable)	Temporal perspective: 1) <i>Prospective during clinical treatment</i> 2) <i>Retrospective (chart review)</i> 3) <i>Retrospective (database);</i> Study period [months]	Definition of ‘drug-related problems’	Selection by ... clinical condition	admissions a) Circumstances of admission o <i>Admission via ED</i> o <i>Only acutely admitted inpatients;</i> b) Minimum duration of stay; c) Repeated ad-missions: Explicitly o <i>Included</i> o <i>Excluded</i>	age or defined age categories	Methods of ... monitoring DRP: <i>Intensively monitored (chart review / assessment) by study staff vs. routinely monitored (origin of collected data from routine healthcare processes (→ patient charts / discharge diagnosis / E-codes))</i>	causality assessment (between drug and problem) Level of causality 1) ≥ <i>probable / certain</i> 2) ≥ <i>possible / likely</i> 3) ≥ <i>conditional / doubtful</i> 4) <i>else</i>	prevent-ability assessment	a) Total number of evaluated paediatric admissions or visits b) Age of the total paediatric study population [years] c) Gender % male	Information on clinical characteristics a) Length of hospital stay (LOS) [days] b) Number of medications per admissions c) Main drug (classes) used (in more than 10% of admissions)
McDonnell 2002 ^{37 a} ; [1999]; US (0.794)	1) Inpatient hospital departments (Paediatrics as subgroup)	2) Retrospective; [11 months]	ADR, WHO definition ⁵³	NR	a) NR; b) NR; c) NR	≤ 15 years	Identification using routine data + routine voluntary reporting using triggers	Naranjo algorithm ⁵⁶ ; 1) ≥ probable / certain	NA	a) 2 046 b) NR c) 50.9%	a) NR b) NR c) NR
Duczmal 2006 ^{38 a,b} ; [1999]; Poland (0.701)	1) Inpatient paediatric hospital department	2) Retrospective; [84 months]	‘ADR’	NR	a) NR; b) NR; c) NR	‘Paediatric’	No clear information, probably: Routine diagnostic in clinical practice	NR	NA	a) 4 996 b) NR c) NR	a) NR b) NR c) NR
Impicciatore 2002 ^{39 b} ; [≤ 2002]; Italy (0.761)	1) Inpatient paediatric hospital department	1) Prospective; [9 months]	‘ADR’	NR	a) NR; b) NR; c) NR	‘Paediatric’	NR	NR	NA	a) 1 619 b) NR c) NR	a) NR b) NR c) NR

Table 1d. Study characteristics and descriptive results of STUDIES WITH A NARROWER CONCEPT OF ‘ADVERSE DRUG REACTIONS’, ‘BASED ON ROUTINE MONITORING’											
Studies; End of data collection [year]; Country (SDI)	General information on the study design			Study population: Inclusion criteria			Methods of data collection			Descriptive outcomes on the paediatric patients	
	Setting 1) <i>Inpatient hospital departments</i> 2) <i>Emergency departments</i> (multicentre if applicable)	Temporal perspective: 1) <i>Prospective during clinical treatment</i> 2) <i>Retrospective (chart review)</i> 3) <i>Retrospective (database);</i> Study period [months]	Definition of ‘drug-related problems’	Selection by ... clinical condition	admissions a) Circumstances of admission o <i>Admission via ED</i> o <i>Only acutely admitted inpatients;</i> b) Minimum duration of stay; c) Repeated ad-missions: Explicitly o <i>Included</i> o <i>Excluded</i>	age or defined age categories	Methods of ... monitoring DRP: <i>Intensively monitored (chart review / assessment) by study staff vs. routinely monitored (origin of collected data from routine healthcare processes (→ patient charts / discharge diagnosis / E-codes))</i>	causality assessment (between drug and problem) Level of causality 1) <i>≥ probable / certain</i> 2) <i>≥ possible / likely</i> 3) <i>≥ conditional / doubtful</i> 4) <i>else</i>	prevent-ability assessment	a) Total number of evaluated paediatric admissions or visits b) Age of the total paediatric study population [years] c) Gender % male	Information on clinical characteristics a) Length of hospital stay (LOS) [days] b) Number of medications per admissions c) Main drug (classes) used (in more than 10% of admissions)
Van der Hooft 2008 ⁴⁰ ; [2003]; The Netherlands (0.842)	o Information on hospitalisations from digital medical patient records of general practitioners (Paediatrics as subgroup)	3) Retrospective (database: IPCI project, general practice research database); [12 months]	ADR, defined by study author	NR	a) Acutely admitted; b) NR; c) NR	≤ 16 years	Identification and classification using routine data	Expert judgement (WHO classification ⁵⁷); 1) <i>≥ probable / certain</i>	NA	a) 301 b) NR c) NR	a) NR b) NR c) NR
Le 2006 ⁴¹ ; [2004]; US (0.811)	1) Inpatient paediatric hospital departments (NICU, PICU, general paediatrics unit, haematology/ oncology)	2) Retrospective; [120 months]	ADR, WHO definition ⁵³	NR Inclusion: Various wards + ICU patients	a) NR; b) NR; c) NR	‘Paediatric’	Identification and classification using routine data	Expert judgement: criteria defined by study authors; ≥ conditional / doubtful	NA	a) NR b) NR c) NR	a) NR b) NR c) NR
Speranza 2008 ^{42 a,b} ; [2007]; Uruguay (0.642)	1) Inpatient paediatric hospital departments	o NR; [0.2 months]	‘ADR’	NR	a) NR; b) NR; c) NR	‘Paediatric’	NR	Algorithm, see Karch et al ⁶³ ; ≥ conditional / doubtful	NA	a) 173 b) NR c) NR	a) NR b) NR c) NR
Moschini 2013 ^{43 b} ; [2013]; Italy (0.787)	2) Paediatric emergency department	1) Prospective; [30 months]	‘ADR’	NR	a) via ED; b) NR; c) NR	‘Paediatric’	Identification and classification using routine data	NR	NA	a) NR b) NR c) NR	a) NR b) NR c) NR
Mendoza 2015 ^{44 b} ; [≤ 2015]; Spain (0.756)	1) Inpatient paediatric hospital departments	2) Retrospective; [132 months]	‘ADR’	NR	a) NR; b) NR; c) NR	≤ 17 years	Routine diagnostic in clinical practice	NR	NA	a) 73 864 b) NR c) NR	a) NR b) NR c) NR
Lombardi 2018 ⁴⁵ ; [2016]; Italy (0.794)	2) Paediatric emergency department	2) Retrospective; [60 months]	‘ADR’	NR	a) via ED; b) NR; c) NR	‘Paediatric’	Identification and classification using routine data	Naranjo algorithm ⁵⁶ ; 3) <i>≥ conditional / doubtful</i> (except for vaccines: “Associable, undefined, not associable”)	NA	a) 221 528 b) NR c) NR	a) NR b) NR c) NR
Morales-Ríos 2020 ⁴⁶ ; [2017]; Mexico (0.640)	1) Inpatient paediatric hospital departments	2) Retrospective; [48 months]	ADR, WHO definition ⁵³	NR	a) NR; b) NR; c) NR	‘Paediatric’	Voluntary documentation during pharmacovigilance program	Naranjo algorithm ⁵⁶ ; 3) <i>≥ conditional / doubtful</i>	NA	a) NR b) NR c) NR	a) NR b) NR c) NR

Table 1a. Study characteristics and descriptive results of STUDIES WITH A BROADER CONCEPT OF ‘ADVERSE DRUG EVENTS’, ‘WITH INTENSIVE MONITORING’ (yellow background)

Table 1b. Study characteristics and descriptive results of STUDIES WITH A BROADER CONCEPT OF ‘ADVERSE DRUG EVENTS’, ‘BASED ON ROUTINE MONITORING’ (orange background)

Table 1c. Study characteristics and descriptive results of STUDIES WITH A NARROWER CONCEPT OF ‘ADVERSE DRUG REACTIONS’, ‘WITH INTENSIVE MONITORING’ (green background)

Table 1d. Study characteristics and descriptive results of STUDIES WITH A NARROWER CONCEPT OF ‘ADVERSE DRUG REACTIONS’, ‘BASED ON ROUTINE MONITORING’ (blue background)

^a study identified via citation search; ^b just abstract of the study available

Abbreviations: NR Not reported, NA Not applicable, SDI Socio-Demographic Index, considered year = End of data collection)⁶⁶, ED Emergency department, DRP Drug-related problem, DRH Drug-related hospitalisation, ADE Adverse drug event, ‘ADE’ ADE was not defined, ADR Adverse drug reaction, ‘ADR’ ADR was not defined, ME Medication error, LOS Length of hospital stay, min = Minimum, max Maximum, CI Confidence interval

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