

**Appendix Table 2. Characteristics of Included Studies from Random or Consecutively Selected Cohorts**

Study	Setting	Study Method	Cohort	How AE Determined	Screening Criteria	Definition of AE	How Diagnostic Error Determined	Definition of Diagnostic Error	% of Admissions Screen Positive	Included Events Before/After admission	Inter-rater Reliability
<b>Cohort studies that report prevalence of diagnostic error</b>											
<b>Wilson, 1995</b>	28 hospitals, Australia	Retro-spective cohort	Random sample, excluded psychiatric, admits <24hours	1.Two stage review 2.MD rates 1-6 scale for causality, ≥4=AE	18 HMPS criteria	1.Injury 2.Caused by health care 3.Prolonged LOS, death, or disability	Type of AE classified by reviewer into 11 categories	Delayed or missed diagnosis	43.7%	Yes, before and after	Kappa 0.55 for AE
<b>Thomas, 2000</b>	27 hospitals, United States	Retro-spective cohort	Random sample, excluded substance abuse, psychiatric	1.Two stage review 2.MD rates 1-6 scale for causality, ≥4=AE	18 criteria based on HMPS	1.Injury 2.Caused by health care 3.Prolonged LOS or disability at time of discharge	Type of AE classified by reviewers into 11 categories	Delayed or incorrect diagnosis	19.5%	Yes before, not after	Kappa 0.4 for AE
<b>Neale, 2001</b>	2 hospitals, England	Retro-spective cohort	Random sample, excluded pediatric, obstetric	1.Two stage review 2.MD rates 1-6 scale for causality, ≥4=AE	18 criteria based on HMPS	1.Injury 2.Caused by health care 3.Prolonged LOS or disability at time of discharge	Type of AE classified by reviewer into 7 categories	Delayed or incorrect diagnosis	NR	Yes, before and after	NR, used single reviewer
<b>Davis, 2003</b>	13 hospitals, New Zealand	Retro-spective cohort	Random sample, excluded psychiatric, admits <24hours	1.Two stage review 2.MD rates 1-6 scale for causality, ≥4=AE	18 criteria based on HMPS	1.Injury 2.Caused by health care 3.Disability	Type of AE classified by reviewer into 7 categories	NR	NR	Yes, before and after	Kappa 0.47 for AE
<b>Baker, 2004</b>	19 hospitals, Canada	Retro-spective cohort	Random sample, excluded pediatric, psychiatric, obstetric, admits <24hours	1.Two stage review 2.MD rates on 1-6 scale for causality, ≥4=AE	18 criteria based on HMPS	1.Injury 2.Caused by health care 3.Prolonged LOS, death or disability at time of discharge	Type of AE classified by reviewer into 10 categories	NR	40.4%	Yes, before and after	Kappa 0.45 for AE

<b>Forster, 2004</b>	2 hospitals, Canada	Retro-specific cohort	Random sample, excluded pediatric, psychiatric	1.Two stage review 2.MD rates on 1-6 scale for causality, $\geq 4=AE$	16 criteria based on HMPS	1.Poor patient outcomes 2.Caused by health care	Type of AE classified by reviewer into 8 categories	Indicated test not ordered or misinterpreted	62.2%	Yes, before, not after	Kappa 0.5 for AE
<b>Sari, 2007</b>	Single trust, England	Retro-specific cohort	Random sample, excluded pediatric, psychiatric, obstetric, neurology	1.Two stage review 2.MD rates on 1-6 scale for causality, $\geq 4=AE$	18 criteria based on HMPS	1.Injury 2.Caused by health care 3.Prolonged LOS, cost or disability at discharge	Type of AE classified by reviewer into 10 categories	NR	44.5%	Yes, before and after	Kappa 0.64 for AE
<b>Aranaz-Andres, 2008</b>	24 hospitals, Spain	Retro-specific cohort	Random sample, excluded admits <24hours	1.Two stage review 2.MD rates on 1-6 scale for causality, $\geq 4=AE$	19 criteria based on HMPS	1.Injury 2.Caused by health care 3. Prolonged LOS, disability at discharge, death	Type of AE classified by reviewer into 6 categories	Delayed or incorrect diagnosis	31.2%	Yes, before and after	Kappa range of 0.431 to 0.868 for different reviewers
<b>Asavaroen gchai, 2009</b>	Single hospital, Thailand	Retro-specific cohort	Random sample of pediatric, internal medicine, obstetric and surgery	1.Two stage review 2.MD determine Y/N AE	52 IHI GTT criteria	1.Injury 2.Caused by health care	Type of AE classified by reviewer using list of 6 categories	NR	NR	unclear	No IRR for physician reviews
<b>Mendes, 2009</b>	3 hospitals, Brazil	Retro-specific cohort	Random sample, excluded pediatric, psychiatric, admits <24hours	1.Two stage review 2.MD rates on 1-6 scale for causality, $\geq 4=AE$	18 criteria based on HMPS	1.Injury 2.Caused by health care 3. LOS, death or disability	Type of AE classified by reviewer into 9 categories	NR	41.0%	Yes, before and after	No IRR for physician reviews
<b>Soop, 2009</b>	28 hospitals, Sweden	Retro-specific cohort	Random sample, excluded psychiatric, palliative care, admits <24hours	1.Two stage review 2.MD rates on 1-6 scale for causality, $\geq 4=AE$	18 criteria based on HMPS	1.Injury 2.Caused by health care 3.Prolonged LOS, death, disability at discharge	Type of AE classified by reviewer into 4 categories	Delayed diagnosis, wrong diagnosis, incomplete diagnosis	33%	Yes, before and after	Kappa 0.80 for AE
<b>Landrigan, 2010</b>	10 hospitals,	Retro-specific cohort	Random sample, excluded	1.Two stage review	52 IHI GTT criteria	NR	Type of AE classified by reviewer	NR	NR	Yes, before, not after	Kappa for reviewers ranged

	United States		psychiatric, pediatric, admits <24hours	2.MD determine Y/N AE			into 7 categories				from 0.64 to 0.93 for AE
<b>Letaief, 2010</b>	Single hospital, Tunisia	Retro-spective cohort	Random sample, no exclusions	1.Two stage review 2.MD determine Y/N AE	18 criteria based on HMPS	1.Injury 2.Caused by health care	Type of AE classified by reviewer into 5 categories	NR	15.0%	Yes, before and after	Kappa 0.82 for AE
<b>Limon-Ramirez, 2012</b>	8 hospitals, Spain	Retro-spective cohort	Random sample, no exclusions	1.Two stage review 2.MD rates on 1-6 scale for causality, $\geq 4=AE$	19 criteria based on HMPS	1.Injury 2.Caused by health care	Type of AE classified by reviewer into 6 categories	NR	12.7%	Yes before, not after	NR
<b>Wilson, 2012</b>	26 hospitals, 8 countries in Africa and Middle East	Retro-spective cohort	Random selection, no exclusions	1.Two stage review 2.MD rates on 1-6 scale for causality, $\geq 4=AE$	18 criteria based on HMPS	1.Injury 2.Caused by health care 3. LOS, death or any disability	Type of AE classified by reviewer into 10 categories	Delayed or incorrect diagnosis	21.6%	Yes, before and after	NR for physician review
<b>Martinez-Mondejar, 2013</b>	Single hospital, Spain	Retro-spective cohort	Random selection of internal medicine, surgery and obstetric	1.Two stage review 2.MD rates on 1-6 scale for causality, $\geq 4=AE$	NR	1.Injury 2.Caused by health care 3. LOS, death or any disability	Type of AE classified by reviewer into 7 categories	NR	38%	Yes before, not after	NR
<b>Lancis-Sepulveda, 2014</b>	Single hospital, Chile	Retro-spective cohort	Consecutive admissions, no exclusions	1.Two stage review 2.MD rates on 1-6 scale for causality, $\geq 4=AE$	19 criteria based on HMPS	NR	Type of AE classified by reviewer into 6 categories	NR	13.6%	Yes before, not after	NR
<b>Akbari Sari, 2015</b>	4 hospitals, Iran	Retro-spective cohort	Random selection, no exclusions	1.Two stage review 2.MD rates on 1-6 scale for causality, $\geq 4=AE$	18 criteria based on HMPS	1.Injury 2.Caused by health care	Type of AE classified by reviewer into 9 categories	Delayed or incorrect diagnosis	38.2%	Yes before, not after	NR
<b>Wang, 2016</b>	Single hospital, Taiwan	Retro-spective cohort	Random sample, no exclusions	1.Administrator screen for	25 criteria based on HMPS	1.Injury 2.Caused by health care	Type of AE classified by reviewer	Delayed or incorrect diagnosis	5.0%*	Yes, before and after	NR

				certain criteria 2.NP review positive screens 3.MD review determines Y/N AE			into 7 categories				
<b>Rafter, 2017</b>	18 hospitals, Ireland	Retro-spective cohort	Random sample, excluded pediatric, psychiatric, obstetric, admits <24hours	1.Two stage review 2.MD rates on 1-6 scale for causality, ≥4=AE	18 criteria based on HMPS	1.Injury 2.Caused by health care 3.Prolonged LOS, death, disability at discharge <sup>11</sup>	Type of AE classified by reviewer into 10 categories	NR	45.0%	Yes, before and after	Kappa 0.52 for AE
<b>Aranaz-Andres, 2017</b>	58 hospitals, Argentina, Columbia, Costa Rica, Mexico, Peru	Retro-spective cohort	Random sample, no exclusions	1.Two stage review 2.MD rates on 1-6 scale for causality, ≥4=AE	19 criteria based on HMPS	1.Injury 2.Caused by health care	Type of AE classified by reviewer into 10 categories	NR	44.5%	Yes, before, not after	NR
<b>Halfon, 2017</b>	Single hospital, Switzerland	Retro-spective cohort	Random sample, excluded psychiatric and obstetric	1.Two stage review 2.MD determines Y/N AE	19 criteria based on HMPS	1.Injury 2.Caused by health care	Type of AE classified by reviewer into 5 categories	NR	33.7%	Yes, before and after	Kappa 0.75 for AE
<b>Cross-sectional studies that report one day prevalence of AE</b>											
<b>Aranaz-Andres, 2011</b>	58 hospitals, Argentina, Columbia, Costa Rica, Mexico, Peru	Retro-spective cohort	Random sample, no exclusions	1.Two stage review 2.MD rates on 1-6 scale for causality, ≥4=AE	19 criteria based on HMPS	1.Injury 2.Caused by health care	Type of AE classified by reviewer into 6 categories	Error or delay in diagnosis	44.5%	Yes before, not after	NR
<b>Mendes, 2018</b>	4 hospitals, Brazil	Retro-spective cohort	Random sample, no exclusions	1.Two stage review 2.MD rates on 1-6 scale for causality, ≥4=AE	19 criteria based on HMPS	1.Injury 2.Caused by health care	Type of AE classified by reviewer into 6 categories	NR	27.5%	No	NR

Abbreviations: AE, adverse event; MD, Doctor of Medicine; NR, not reported; HMPS, Harvard Medical Practice Study; Y/N, yes or no; IHI GTT, Institute for Healthcare Improvement Global Trigger Tool; IRR, inter-rater reliability.

\*2.2% of admissions were screen positive in the study, but authors also reviewed an additional group of negative screen admissions randomly for a total of 5% of all admissions