

Online Supplement

Summary of studies included in the review

This supplement provides a summary of each of the studies identified for the review and their quality (rated using validated appraisal tools).

For systematic reviews, quality was assessed using the Critical Appraisal Skills Programme (CASP) tool. For observational (epidemiological and other) studies, quality was assessed using the Evidence Based Library and Information Practice (EBLIP) Critical Appraisal Checklist.

The table is ordered alphabetically.

Findings are listed in terms of:

- the number of safety incidents
- the type of safety incidents
- the level of harm associated with incidents

Not all studies included findings in each of these areas, so parts of the table are left blank if there were no relevant key findings.

Studies included in systematic reviews

Studies summarized in systematic reviews identified as part of this review are listed in alphabetical order. This is to illustrate the range of studies drawn on, even if the original primary studies were not incorporated into the narrative synthesis for our review.

Online content

The final page of this document lists where the full protocol can be found online (including the full search terms and search strategy) as well as where freely available online content can be sourced.

Online table 1: Summary of key findings of studies included in the review

First author	Study type	Setting	Country	Measurement method	Number of safety incidents	Type of safety incidents	Harm associated with incidents	Quality rating
Abramson 2012 ¹	Observational	Primary care clinic	USA	Review of prescriptions	Reviewed 9385 prescriptions from 78 providers and found 36.7 prescribing incidents per 100 prescriptions (95% CI 30.7 to 44.0), excluding incidents associated with legibility. Non-legibility incidents were found in 175.0 per 100 prescriptions (95% CI 169.1 to 181.3), inappropriate abbreviation incidents in 13.4 and direction incidents in 4.2 per 100 prescriptions. The majority of incidents were judged to be preventable.			Moderate
Abramson EL 2013 ²	Observational	Primary care	USA	Record review	Chart review of patient notes from 16 clinicians over a three month period analysed 1905 prescriptions. The prescribing incident rate was 3.8 per 100 prescriptions (95% CI 2.8 to 5.1).			Low
A-Elgayoum SME 2009 ³	Observational	Primary care clinic	Sudan	Test review	3203 blood smears from patients clinically suspected to have malaria were examined. Of these 2253/3203 (70.3%) were found to be a misdiagnosis.			Moderate
Al Khaja KA 2011 ⁴	Observational	Primary care clinics and pharmacy	Bahrain	Review of prescriptions	Audited prescriptions issued by 20 primary care centers and found 733/2773 (26.4%) medical prescribing incidents.			Moderate

First author	Study type	Setting	Country	Measurement method	Number of safety incidents	Type of safety incidents	Harm associated with incidents	Quality rating
Al Khaja KAJ 2007 ⁵	Observational	Primary care clinics	Bahrain	Review of prescriptions		Incidents in prescriptions included 4972/7139 (69.7%) incidents of omission such as strength/dose: 573/4972 (11.5%); dosage form: 2815/4972 (56.6%); dosage frequency: 261/4972 (5.3%); and length of treatment: 1323/4972 (26.6%). Incidents of commission accounted for 1759/7139 (24.6%) of incidents in prescriptions. These included dosage form: 159/1759 (9.0%); dosage frequency: 105/1759 (6.0%); and length of treatment: 1419/1759 (80.7%).		Moderate
Al Khaja KAJ 2007 ⁶	Observational	Primary care clinic	Bahrain	Review of prescriptions	2282 prescriptions dispensed for infants for corticosteroids were analyzed. The frequency of dosing and length of therapy were not stated in 21.6% and 43.6% of prescriptions, respectively.			Moderate

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Al Khaja KAJ 2007 ⁷	Observational	Primary care clinic	Bahrain	Review of prescriptions	Reviewed prescriptions for infants. Drug-related incidents were present in 2066/2282 (90.5%) of the prescriptions reviewed. 5745 prescribed drug items were reviewed. There were 4282/5745 (74.5%) drug-related incidents.	Incidents of omission accounted for 4146/5745 (72.2%) of drug-related incidents. The breakdown of this category was: strength/dose: 424/4146 (10.2%); dosage form: 979/4146 (23.6%); dosage frequency: 621/4146 (15.0%); and length of treatment: 2122/4146 (51.2%). Incidents of commission accounted for 3338/5745 (58.1%). The breakdown of this category was: dosage form: 1354/3338 (40.6%); dosage frequency: 4/3338 (0.1%); length of treatment: 1594/3338 (47.8%); and incidents of commission: 386/3338 (11.6%). Incidents of integration accounted for 183/5745 (3.2%).		Moderate
Al Khaja KAJ 2010 ⁸	Observational	Primary care clinics and pharmacy	Bahrain	Review of prescriptions	Audited prescriptions issued by 20 primary care centers for pediatric iron preparations. Found 75/86 (87.2%) of prescriptions contained omission incidents.	Omission incidents were subcategorized as: unclear names of iron preps: 15/75 (20.0%); prescriptions without specifying the daily dosage of iron: 4/75 (5.3%); prescriptions without stating the daily dosage of iron: 42/75 (56.0%); and prescriptions without specifying the duration of therapy: 14/75 (18.7%).		Moderate

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Al-Agilly S 2007 ⁹	Observational	General practice	UK	Record review	Patients were invited to check their records. 187 out of 258 patients (72.5%) said their records were accurate. There were 89 inaccuracies reported by patients. 42 (47%) were of obvious clinical importance including wrongly entered diagnoses, or missing major morbidity such as an operation, or incidents in repeat medication. There were 47 (53%) inaccuracies in lifestyle data (smoking, alcohol history or weight), or dates of illnesses.			Moderate
Apeas 2008 ¹⁰	Observational	Primary care clinic	Spain	Incident reporting system	Of 96,047 visits, the health care professional detected some possible adverse effect in 1,932 visits, generating a total of 2,059 reports. A total of 1,074 adverse effects were identified corresponding to 971 different patients. The prevalence of adverse effects per visit was 11.18% (1,074/96,047, 95% CI 10.52% to 11.85%). The prevalence of visits which experience some adverse event was 17.93% (1,722/96,047, 95% CI 17.09% to 18.77%).	The causes of these incidents included medication (534/1180, 45.3%), provision of care (285/1080, 26.4%), communication (273/1080, 25.3%), diagnosis (159/1080, 14.7%) and management (99/1080, 9.2%).	In 23.6% of the cases, the consequences of the adverse effect did not affect the care provided, in 33.1% a higher level of observation and monitoring were required, in the remaining 7.5%, the adverse effect required an additional test and in 17.1%, an additional medical or surgical treatment was performed. In 14.9%, the consequence of the adverse effect required another visit or referral to specialized care (without hospitalization), and in 5.8% hospitalization of the patients for some life support treatment was required. 778 / 1108 (70.2%) adverse events were deemed to be preventable and 330/1108 (29.8%) could not have been prevented.	High

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Aranaz-Andrés JM 2012 ¹¹	Observational	General practice	Spain	Record review and survey	Data were collected for 52 healthcare professionals who attended 96,047 consultations. 773 adverse events were identified, giving a point prevalence of 0.8% (95% CI 0.76 to 0.85).	55.5% (429) of the AE stemmed from problems with the medication prescribed; 17.1% (132) involved a worsening of the clinical course of the underlying disease; 7.8% (60) involved complications from a medical procedure; 7.4% (57) involved health care-related infection; and 6.1% (50) stemmed from problems with the care dispensed (wound cures, catheter care, etc).	Most adverse events (64.3%) were considered preventable and only 5.9% were severe, usually related to medication (odds ratio 4.6; 95% CI 2.1 to 10.3).	Low
Avery AJ 2013 ¹²	Observational	General practice	UK	Record review	6048 unique items prescribed over a 12 month period for 1777 patients were examined. 4.9% of all prescription items had a prescribing or monitoring incident (95% CI 4.4% to 5.5%).		Most incidents were of mild to moderate severity. 0.2% were classed as severe. Children under 15 years, adults over 64 years and people with higher numbers of unique medication items prescribed were at greater risk of incidents.	Moderate
Beyer M 2003 ¹³	Observational	General Practice	Germany	Incident reporting system		Examined 51 medication incidents. These were subcategorized as follows: failure to give medicine: 3/51 (5.9%); wrong medication: 8/51 (15.7%); wrong dose: 9/51 (17.7%); drug omitted: 1/51 (2.0%); adverse events: 6/51 (11.8%); drug interactions: 6/51 (11.8%); other: 10/51 (19.6%); no indication: 8/51 (15.7%).		Low

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Beyer M 2005 ¹⁴	Observational	General practice	Germany	Incident reporting system		Analyzed 85 incident reports. These included wrong diagnosis: 17/85 (20.0%); wrong clinical decision: 9/85 (11.0%); not applicable: 1/85 (1.0%); administration incidents: 9/85 (11.0%); investigation incidents: 2/85 (2.0%); treatment incidents: 23/85 (27.0%); communication incidents : 18/85 (21.0%); wrong payment: 4/85 (5.0%); wrong treatment: 2/85 (2.0%).	34% of incidents caused temporary or permanent harm.	Moderate
Bhasale A 1998 ¹⁵	Observational	General practice	Australia	Incident reporting system		Types of diagnostic incident included: missed diagnosis: 59/142 (41.6%); misdiagnosis: 38/142 (26.8%); delayed diagnosis: 31/142 (21.8%); and diagnostic procedural complication: 18/142 (12.7%). Contributing factors were listed as: incident in judgment: 63/142 (44.4%); failure in recognizing signs and symptoms: 57/142 (40.1%); poor communication between patient and health team: 33/142 (23.2%); poor communication between health professionals: 30/142 (21.1%); inappropriate action of others: 30/142 (21.1%); inappropriate patient assessment: 27/142 (19.0%); inappropriate follow up of patient: 19/142 (13.4%); and inappropriate second opinion : 33/142 (23.2%).	60/142 (42.3%) patients suffered no harm; 36/142 (25.4%) suffered low harm; 15/142 (10.6%) suffered moderate harm; 12/142 (8.5%) suffered severe harm; and that 19/142 (13.4%) patients died.	Moderate
Bradbury F 2004 ¹⁶	Observational	General practice	Ireland	Record review	Of the 8830 patient records reviewed for people using NSAIDs, 1462/8830 (16.6%) showed evidence of an adverse drug reaction.			Moderate

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Bradley MC 2012 ¹⁷	Observational	Primary care	UK	Database	The overall prevalence of potentially inappropriate prescribing in over 70 year olds (n =166,108) was 34%.			Moderate
Bregnhøj L 2007 ¹⁸	Observational	General Practice	Denmark	Records review	212 older people with polypharmacy were prescribed 1621 medications by their GPs. 640/1621 (39.5%) of the medications were likely to be inappropriate. Most of the patients (200/212, 94.3%) had one or more inappropriate ratings among their medications.			High
Brekke M 2008 ¹⁹	Observational	General practice	Norway	Record review	15,790/86,000 (18.4%) elderly people received one or more potentially harmful medications / inappropriate prescriptions from their GP.			Moderate
Brenner S 2012 ²⁰	Observational	Primary and urgent care	US	Record review	A trigger tool identified that 15% of patients had adverse drug events.	54% of adverse drug events occurred during medication monitoring, and 45% during patient self-administration.		Moderate

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Britt H 1997 ²¹	Observational	General practice	Australia	Incident reporting system		Examination of 500 incident reports found pharmacological treatments: 259/500 (51.8%); non-pharmacological treatments: 183/500 (36.5%); diagnostic incidents; 142/500 (28.3%); equipment incidents: 26/500 (5.2%); poor communication: 130/500 (26.0%); incident in judgment: 120/500 (24.0%); action of others: 120/500 (24.0%); poor communication between health professionals: 100/500 (20.0%); patient consulted other medical officer: 80/500 (16.0%); failure to recognize symptoms: 70/500 (14.0%); patients history not adequately reviewed: 55/500 (11.0); omission of checking procedure: 55/500 (11.0%); and GP tired/rushed/running late: 50/500 (10.0%).		Moderate
Casalino LP 2009 ²²	Observational	Primary care	USA	Record review	Retrospective medical record review of 5434 randomly selected patients aged 50 to 69 years in 19 community-based and 4 academic medical center primary care practices found the rate of apparent failures to inform people of an abnormal test result or to document informing the patient was 7.1% (135 failures / 1889 abnormal results), with a range of 0% to 26.2%.			Moderate
Clark RC 2007 ²³	Observational	General practice	UK	Record review	127,582,000 patient records were reviewed and adverse drug reactions were found in 3,968,000/127,582,000 (3.1%) cases.			Moderate

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Cox SJ 2004 ²⁴	Observational	General practice	UK	Significant Event Audit		This study analyzed significant events. Administrative incidents made up the highest proportion of events: 95/337 (28.2%). Other events were categorized as follows: other medical: 70/337 (20.8%); prescribing-related events: 46/337 (13.7%); missed new cancer diagnosis: 32/337 (9.5%); other: 28/337 (8.31%); nursing-related events: 23/337 (6.8%); patient complaint: 17/337 (5.0%); avoidable death where terminal care took place at home: 15/337 (4.5%); section under Mental Health Act: 8/337 (2.4%); and suicide: 3/337 (0.89%).		Low
De Wet C 2009 ²⁵	Observational	General practice	UK	Record review	Review of 500 records found an adverse event in 47 records (9.4%), indicating that harm occurred at a rate of one event per 48 consultations. A further 17 records (3.4%) contained evidence of a potential adverse event.	Incident and harm rates were higher in those aged >60 years, and most were medication-related (59%).	Harm severity was low to moderate for most patients (82.9%).	Moderate
De Wilde S 2007 ²⁶	Observational	General practice	UK	Record review	Looked at 171,690 records of elderly people and found 55,325 / 171,690 (32.2%) patients received potentially inappropriate medications.			Moderate
Diamond MR 1995 ²⁷	Observational	General practice	Australia	Interviews		Interviews with 39 trainees in general practice found that of 180 incident reports 70/180 (38.9%) were related to communication; 17/180 (9.4%) were related to management; 56/180 31.11% to diagnosis; 17/180 9.44% to administration; and 20/180 11.11% were classified as 'other'.		Low

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Dovey SM 2002 ²⁸	Observational	Family practice	USA	Incident reporting system		<p>Knowledge and skills incidents made up 46/330 (13.9%) of medical incidents. Process incidents accounted for 284/330 (86.1%) of medical incidents. The process incidents were further broken down as: office administration: 102/284 (35.9%); investigations: 82/284 (28.9%); treatment 76/284 (26.8%); communication: 19/284 (6.7%); and insurance-related incidents: 1/284 (0.4%). When looking at incident reports, process incidents made up 284/330 (86.1%) of incident reports. The process incidents were further broken down as: office administration: 102/284 (35.9%); investigations: 82/284 (28.9%); other investigations: 6/284 (2.11%); treatments: 76/284 (26.8%); communication: 19/284 (6.7%); payment: 4/284 (1.4%). Knowledge and skill incidents made up 46/330 (13.9%) of incident reports.</p>	184/330 (55.8 %) incident reports recorded that the patient suffered no harm; 40/330 (12.1%) reports showed that the patient suffered low harm; 23/330 (7.0%) reports showed that the patient suffered moderate harm; 18/330 (5.5%) reports showed that the patient suffered severe harm; and 1/330 (0.3%) report recorded the death of a patient.	Moderate
Eggleton KS 2014 ²⁹	Observational	General practice	New Zealand	Record review	Harm was identified in 46 out of 170 patient records (27%). This equates to 7 occurrences of harm per 100 consultations.	All harms related to medication use.		Low

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Elder NC 2002 ³⁰	Systematic review	Primary care	USA	Various		Four studies described medical incidents and adverse events in primary care, and three other studies peripherally addressed primary care medical incidents. There were three main types of preventable adverse events: diagnosis, treatment, and preventive services. Process incidents were classified into four categories: clinician, communication, administration and blunt end.		High
Elder NC 2004 ³¹	Observational	Family practice	USA	Survey	Fifteen physicians in 7 practices completed forms for 351 visits. Incidents and preventable adverse events were identified in 24% of these visits. There was wide variation in how often individual physicians identified incidents (3% to 60% of visits).	57/351 (16.2%) of the reports related to office administration incidents. Of these, 37/57 (64.9%) related to charting; and general office administration accounted for 21/57 (36.8%) incidents. Physician-related incidents accounted for 28/351 (8.0%); patient communication incidents accounted for 16/351; and 15/351 (4.3%) related to preventable adverse events.	Harm was believed to have occurred as a result of 24% of the incidents, and was a potential in another 70%.	Moderate
Ely JW 2012 ³²	Observational	Primary care	USA	Survey		200 family physicians, general internists and general pediatricians were surveyed about diagnostic incidents. Common presenting complaints included abdominal pain (n = 27 of 202 patients, 13%); fever (n = 19; 9%); and fatigue (n = 15, 7%).		Low

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Farrow SC 1999 ³³	Observational	General practice	UK	Survey	This study looked at infection control in general practice. In the 82 practices, it found the following issues. Failure to access an autoclave: 56/82(68.3%); failure to have an autoclave with maintenance contract: 34/82 (41.5%); lack of access to Central Sterile Supply Department: 16/82 (19.5%); ineffective decontamination: 20/82 (24.4%); and inappropriate use of chemical disinfectants: 33/82 (40.24%). It also found a lack of hepatitis B vaccination in exposed staff in 31/82 (37.8%) practices; no infection control guidelines/sharps injury protocols in 60/82 (73.2%) practices; and a lack of training in 54/82 (65.85%) practices.			Low

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Fernald DH 2004 ³⁴	Observational	Primary care	USA	Incident reporting system		Examined reports to primary care incident report system. Diagnostic testing incidents accounted for 325/708 (45.0%) of all incident reports. This was further broken down into: blood test: 129/325 (39.7%); other specimen: 67/325 (20.6%); imaging: 58/325 (17.9%); and 'other or unspecified test': 31/325 (9.5%). Medication incidents accounted for 165/708 (23.3%) of all incident reports. This category was further categorized as follows: wrong drug: 32/165 (19.4%); right drug: wrong dose or timing: 99/ 165 (60.0%); right drug: wrong administration or dispensing: 39/165 (23.6%); drugs not prescribed: 6/165 (3.64%). Communication incidents accounted for 437/708 (61.7%) of all incident reports.	134/209 patients (64.1%) suffered no harm; 32/209 (15.3%) suffered low harm; 21/209 patients (10.1%) suffered moderate harm; and 22/209 patients (10.5%) suffered severe harm.	High
Field TS 2004 ³⁵	Observational	Primary care clinic	USA	Record review and incident reports	Among 31,757 older people, 1,523 adverse drug events were identified, a rate of 48.0 per 1,000 person-years. The rate of preventable adverse drug events was 13.3 per 1,000 person-years.			Moderate

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Gaal S 2011 ³⁶	Observational	General practice	Netherlands	Record review	A random sample of 1,000 patients from 20 general practices was obtained. The 1,000 patient records included a total of 8,401 patient contacts with the practice. A total of 211 patient safety incidents were identified (95% CI 185 to 241). These incidents concerned 186 patients. In other words, a total of 1 to 4 patient safety incidents per patient were detected per year for a prevalence of 2.2% for all patient contacts (186/8401).	116/211 (55.0%) adverse events were related to poor organization. 31/211 (14.7%) were related to treatments; 26/211 (12.3%) were related to communication issues; 21/211 (10.0%) were related to diagnosis; 14/211 (6.6%) were categorized as 'prevention'; and triage accounted for 3/211 (1.4%) adverse events. In terms of cause, 4/358 (1.1%) were categorized as technical; 176/358 (49.2%) as human; 97/358 (27.1%) as organizational; and 81/358 (22.6%) as patient-related.	58 out of 211 patient safety incidents affected patients; seven were associated with hospital admission; none resulted in permanent disability or death. 51/101 (50.5%) of patients suffered low harm; 39/101 (38.6%) suffered no harm; 7/101 (6.9%) suffered moderate harm; and 4/101 (4.0%) were categorized as 'unknown harm'.	Moderate
Garfield S 2009 ³⁷	Systematic review	Primary care	UK	Various		Review of 27 papers to map the medicines management system in primary care in the UK. The proportion of incidents in managing medicines in primary care was high. Several stages of the process had incident rates of 50% or more: repeat prescribing reviews, interface prescribing and communication and patient adherence.		High

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Gehring 2012 ³⁸	Observational	General practice	Switzerland	Survey		Cross-sectional survey of 630 nurses and doctors in 472 practices asking about the occurrence of patient safety incidents and analyzed data from the Swiss primary care critical incident reporting systems. The incidents with highest frequency were incomplete, unavailable, unclear, or incorrect patient documentation (88.4%); missing, incomplete, or erroneous information from external providers (81.7%); and required medication was not prescribed, administered, or dispensed (80.6%).		Low
Gurwitz JH 2003 ³⁹	Observational	Ambulatory care clinic (including primary care)	USA	Record review and incident reports	In 30,397 older person-years there were 1523 adverse drug events. The overall rate of adverse drug events among older people was 50.1 per 1000 person-years, with a rate of 13.8 preventable adverse drug events per 1000 person-years.	Incidents associated with preventable drug events were most often related to prescribing and monitoring.	38% (578) of drug events were categorized as serious, life threatening or fatal.	High
Hansen LB 2006 ⁴⁰	Observational	Primary care	USA	Survey		22 practices recorded 567 clarification calls over a two week period from pharmacies, most frequently for prior authorization issues (n = 209; 37%), formulary issues (n = 148; 26%), and unclear/missing prescription dosages (n = 117; 21%). Drug classes most frequently requiring clarifications were gastrointestinal (n = 122; 21.7%), cardiovascular (n = 278; 13.9%), and analgesic / anesthetic (n = 74; 13.2%) agents.		Low

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Hickner J 2008 ⁴¹	Observational	Family practice	USA	Incident reporting system		Examined 590 event reports of 966 testing process incidents. Incidents occurred in ordering tests (12.9%), implementing tests (17.9%), reporting results to clinicians (24.6%), clinicians responding to results (6.6%), notifying patient of results (6.8%), general administration (17.6%), communication (5.7%) and other categories (7.8%). Charting or filing incidents accounted for 14.5% of incidents.		Moderate
Hickner J 2010 ⁴²	Observational	Primary care clinic	USA	Incident reporting system		507 anonymous event reports were submitted by 24 practices. Of these reports, 357 (70%) included medication incidents only, 138 (27%) involved adverse drug events only, and 12 (2.4%) included both.	Eight (1.6%) of the reported events led to hospitalization.	High
Hildebrandt DE 2006 ⁴³	Observational	Family practice	USA	Record review			Examined level of harm suffered when people were not appropriately triaged when they rang primary care for help out of hours. 31/119 (26.1%) patients suffered low harm (discomfort due to pain); and 4/119 (3.4%) patients suffered moderate harm.	Moderate

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Hoffmann B 2008 ⁴⁴	Observational	General practice	Germany	Incident reporting system		Most of the incident reports (52/78, 66.7%) – related to ‘appropriate care obstructed or delayed/inappropriate care provided’. Within this category, ‘prescribing or medication review’ accounted for 11/52 (21.2%) reports; 10/52 (19.2%) reports related to ‘delays or inappropriate care in hospital. ‘Lack of information, communication failures’ were responsible for 7/52 (13.5%) reports. The rest of the breakdown is as follows: dealing with test results or hospital correspondence: 5/52 (9.6%) reports; referrals (delayed/forgotten): 5/52 (9.6%) reports; vaccination/ drug administration: 4/52 (7.7%) reports; judging urgency of patient’s condition: 2/52 (3.9%) reports; external factors/equipment failures: 3/52 (5.8%) reports; failing to home visit: 2/52 (3.85%); dispensing incidents: 2/52 (3.9%).	‘Actual or potential consequence’ related to 20/78 (25.6%) incident reports. ‘No apparent potential for harm to patients’ related to 3/78 (3.9%) reports; and 3/78 (3.9%) were labelled as ‘other’.	Moderate

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Holden J 1998 ⁴⁵	Observational	General practice	UK	Record review		Audit of 1263 deaths found that GP factors occurred in 65/1263 (5.2%) cases. Within this category, the highest proportion was 25/65 (38.5%) reports related to delayed referral, diagnosis, treatment. This was followed by non-prescription of aspirin: 22/65 (3.9%) reports; failure to check/control blood pressure: 12/65 (18.5%) reports; side-effects from aspirin: 3/65 (4.6%) reports; poor diabetic control: 1/65 (1.5%) report; failure to challenge hospital drug treatment: 1/65 (1.5%) report; and failure to treat osteoporosis: 1/65 (1.5%)		Moderate
Honigman B 2001 ⁴⁶	Observational	Primary and ambulatory care	USA	Record review	There were adverse drug events in 864/25056 (3.5%) of cases. The adverse drug event rate was rate was 5.5 (95% CI 5.2 to 5.9) per 100 patients coming for care.			High
Howard M 2004 ⁴⁷	Observational	Family practice	Canada	Record review	127/777 (16.3%) older people were prescribed one or more potentially inappropriate medications.			Moderate

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Illboudo TP, 2012 ⁴⁸	Observational	Primary care clinic	Burkina Faso	Record review	This study assessed the correctness of diagnoses from 12 health centers among patients with severe malaria and pneumonia. Among the 457 malaria cases affecting children under five, 66 cases (14.4%) were correctly diagnosed and of those 66 correctly diagnosed cases, 40 cases (60.6%) received an appropriate referral decision from their providers. Among the adult pneumonia cases, 5.9% (79/1331) of the diagnoses were correctly diagnosed; however, the appropriateness rate of the provider's referral decision was 98.7% (78/79).			Moderate
Kennedy AG 2008 ⁴⁹	Observational	Primary care	USA	Incident reporting system			216 incident reports were submitted. Nearly 90% (142/165) were incidents that did not reach the patient (low severity). Nineteen incidents reached the patient without causing harm (8.7%) and 4 incidents caused temporary harm requiring intervention (1.8%)..	Moderate
Khoja T 2011 ⁵⁰	Observational	Primary care	Saudi Arabia	Review of prescriptions	This study looked at 5299 prescriptions and found prescription incidents in 990/5299 (18.7%) of cases.		8/990 (0.8%) were classified as serious, and were potentially life-threatening incidents; 369/990 (37.3%) were classified as 'major nuisance'; 86/990 (8.7%) were classified as 'minor nuisance'; and 527/990 were classified as trivial (53.2%).	Moderate

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Khoja TA 1996 ⁵¹	Observational	Primary care	Saudi Arabia	Review of prescriptions	Out of 6350 prescriptions, 11.6% were found to have at least one incident.	Of 20320 individual drug entries, incidents included strength not stated: 772/20320 (3.8%); wrong dose: 329/20320 (1.6%); tablet instead of capsule: 197/20320 (1.0%); quantity and/or frequency missing: 652/20320 (3.2%); drug interactions: 24/20320 (0.1%); contraindication: 59/20320 (0.3%); wrong drug: 193/20320 (1.0%); incomplete drug: 136/20320 (0.7%); frequency of the daily dose missing: 18186/20320 (89.5%); generic name of the drug missing: 17475/20320 (86.0%); strength missing: 15504/20320 (76.3%); illegible/incomplete personal and diagnostic data: 12801/20320 (63.0%); duration of treatment missing: 7681/20320 (37.8%); poor/fair handwriting and abbreviations: 3861/20320 (19.0%); very poor handwriting and abbreviations: 3658/20320 (18.0%); and form of the drug missing: 2723/20320 (13.4%).		Low

First author	Study type	Setting	Country	Measurement method	Number of safety incidents	Type of safety incidents	Harm associated with incidents	Quality rating
Khoo 2012 ⁵²	Observational	Primary care clinic	Malaysia	Record review	A sample of 1753 medical records from 12 primary care clinics were scanned for diagnostic, management and documentation incidents. They found that 3.6% of medical records contained diagnostic incidents (95% CI 2.2 to 5.0), 53.2% contained management incidents (95% CI 46.3 to 60.2), 41.1% contained medication incidents (95% CI 35.8 to 46.4), 21.7% contained investigation incidents (95% CI 16.5 to 26.8), and 14.5% contained decision-making incidents (95% CI 10.8 to 18.2).		39.9% (95% CI 33.1 to 46.7) of incidents were potentially seriously harmful and nearly all (93.5%) were considered preventable.	Moderate
Kingston-Reichers J 2010 ⁵³	Systematic review	Primary care	Canada	Various		Two major forms of harm were missed or delayed diagnosis and medication harm.	Included 46 studies. Proportion of incidents associated with harm was between 9% and 52% in individual studies. Between 42% and 83% were thought to be preventable.	High
Koper 2013 ⁵⁴	Observational	General practice	Austria	Review of prescriptions	Examined medications of 169 patients with polypharmacy in 22 GP clinics. 74 patients (56.2%) had at least one dosing incident, four patients (2.4%) had at least one interaction in the most severe category. 158 patients were elderly (≥65 years), and of these 37.3% (n = 59) had at least one potentially inappropriate medication for the elderly.			Low

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Koper D 2013 ⁵⁵	Observational	General practice	Austria	Record review	The medications of 169 patients with polypharmacy treated in 22 GP surgeries were analysed. Patients took an average of nine medicines each day. At least one dosing incident was found in 56% of patients.			Low
Kostopoulou O 2007 ⁵⁶	Observational	General practice	UK	Incident reporting system		'Appropriate care obstructed or delayed/inappropriate care provided' accounted for 52/78 (66.7%) reports.	78 incident reports were relevant to patient safety and analysable. They included 21 (27%) adverse events and 50 (64%) near misses. 16.7% (13/71) had serious patient consequences, including one death. 75.7% (59/78) had the potential for serious patient harm. 'No apparent potential for harm to patients' accounted for 3/78 (3.9%) incident reports.	Moderate
Kuo GM 2008 ⁵⁷	Observational	Family practice	USA	Incident reporting system		126 out of 194 (70%) medication incidents were prescribing incidents, 17 (10%) were medication administration incidents, 17 (10%) documentation incidents, 13 (7%) dispensing incidents and 5 (3%) were monitoring incidents. Adverse drug events resulted from 16% of reported medication incidents.	Harm from reported incidents was categorised as: prevented and did not reach patients, (72, 41%), reached patients but did not require monitoring (63, 35%), reached patients and required monitoring (15, 8%), reached patients and required intervention (23, 13%) and reached patients and resulted in hospitalisation (5, 3%). No deaths were reported.	Moderate

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Kuzel AJ 2004 ⁵⁸	Observational	Primary care	USA	Interviews		People identified 221 events. The highest proportion of adverse events reported were related to breakdowns in the clinician-patient relationship: 82/221 (37.1%). This was followed by access breakdown: 63/221 (28.5%); and technical incident: 54/221 (24.4%). Communication breakdown related to 17/221 (7.7%) of adverse events; with inefficiency of care accounting for 5/221 (2.3%) of adverse events.	107/221 events had harm (76.9%). 119/170 (70.0%) of the harms were psychological. 39/170 of the harms were physical (22.9%).	Moderate
Leon AC 1999 ⁵⁹	Observational	Primary care	USA	Interviews	This study examined the diagnosis of mental health issues in primary care. It found: misdiagnosis of major depression in 160/1000 (16.0%) patients; and misdiagnosis of panic disorder in 96/1001 (9.6%) patients.			Moderate
Lund BC 2010 ⁶⁰	Observational (part of trial)	Primary care	USA	Survey	Of 236 patients, 34 (14.4%) experienced an adverse drug event.			High
Makeham M 2008 ⁶¹	Systematic review	Primary care	Australia	Various	Review of 49 studies found estimates of patient safety incidents in primary care were 0.004 to 240 per 1000 primary care consultations.	26% to 57% of incidents involved diagnostic "incidents"; 7% to 52% involved treatment; 13% to 47% involved investigations; 9% to 56% involved office administration; 5% to 72% were communication incidents.	45% to 76% of all 'incidents' were preventable. Harm from safety incidents ranged from 1.3 significant minor incidents per 1000 treatments to 4% of incidents resulting in death, 17% to 39% resulting in harm, and 70% to 76% had potential for harm.	High

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Makeham MA 2002 ⁶²	Observational	General practice	Australia, Canada, Netherlands, New Zealand, UK, USA	Incident reporting system		Of 132 incident reports, 104/132 (78.8%) were related to process incidents. Of these, 26/104 (25.0%) related to incidents in office administration; 17/104 (16.4%) related to investigation incidents; 38/104 (36.6%) related to treatment incidents; 20/104 (19.2%) related to communication incidents; 1/104 (1.0%) related to payment incidents; and incidents in health care workforce management accounted for 2/104 (1.9%) of reports. 28 of the 132 incident reports were related to knowledge and skill incidents (21.2%). These were further broken down into: incidents in execution of a clinical task 7/28 (25.0%); incidents in diagnosis: 18/28 (64.3%); wrong treatment decision with right diagnosis: 3/28 (10.7%).		Moderate
Makeham MA 2006 ⁶³	Observational	General Practice	Australia	Incident reporting system	84 GPs submitted 418 incident reports, claimed for 490864 consultations and saw 166569 individuals in one year. The incidence of reported incident per consultation per year was 0.078 (95% CI 0.076% to 0.080%). The incidence of reported incidents per patient seen per year was 0.24% (95% CI 0.235% to 0.245%). Two incidents are reported for every 1000 individual patients seen by a GP.		418/166,569 (0.25%) incidents led to patient harm.	High

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Makeham MA 2008 ⁶⁴	Observational	General Practice	Australia	Incident reporting system		Incidents relating to the processes of healthcare (n=365, 69.5%) were more common than those relating to deficiencies in the knowledge and skills of health professionals (n=160, 30.5%).		High
Martinez Sanchez A 2011 ⁶⁵	Observational	Community pharmacy (review of primary care prescriptions)	Spain	Review of prescriptions	Review of community pharmacy records for primary care indicated prescription incidents in 355/23995 cases (1.5%).	Most incidents were due to incomplete/incorrect information or prescribed items being unavailable: 247/355 (69.6%). Inappropriate doses accounted for 27/355 incidents (7.6%); and inappropriate direction or instruction accounted for 25/355 incidents (7.0%).		Moderate
McKay J 2009 ⁶⁶	Observational	General practice	UK	Significant Event Audit		259 significant event analyses were reviewed with the following breakdown of incidents: disease diagnosis and disease management: 46/259 (17.8%); prescribing, dispensing and other drugs 46/259 (17.8%); patient and relatives: 43/259 (16.6%); investigations and results: 37/259 (14.29%); communication: 23/259 (8.88%); administration: 16/259 (6.18%); medical records and confidentiality: 15/259 (5.79%); appointments and surgeries: 12/259 (4.63%); home visits and external care: 10/259 (3.86%); equipment: 7/259 (2.70%); miscellaneous: 2/259 (0.77%); health and safety: 2/259 (0.77%).	191 reports were reviewed regarding harm. Most patients did not suffer any harm: 109/191 (57.1%); low harm occurred in 14/191 cases (7.33%); moderate harm in 22/191 cases 11.52%; and severe harm in 9/191 cases (4.71%). Three deaths occurred overall: 3/191 (1.57%). 34/191 (17.80%) cases were not classified. The 109 incidents (57.1%) which did not lead to any harm were made up of incidents which had the potential to cause patient harm but were prevented, or incidents that ran to completion without harm occurring – ‘near misses’.	Moderate

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McKay J 2013 ⁶⁷	Observational	General practice	UK	Record review	Twenty-one GP trainees attended a two hour workshop about how to use a trigger tool to identify patient safety incidents and then reviewed 25 clinical records each. 80 out of 520 records (15%) identified previously undetected patient safety incidents.		30 out of these 80 incidents were judged potentially preventable (45%). 35 were judged to cause moderate to severe harm (44%).	Low
Miller GC 2006 ⁶⁸	Observational	General practice	Australia	Incident reporting system	852/8215 patients (10.4%) suffered adverse events.		Harm to patients was recorded as: mild: 297/551 (53.9%); moderate: 197/551 (35.8%); severe: 55/551 (10.0%); and 'don't know': 2/551 (0.4%).	Low
Montastruc P 1993 ⁶⁹	Observational	Primary care clinic	France	Record review		49 adverse events identified in a rural area over a one year period were reviewed. Cutaneous adverse drug reactions accounted for 15/49 (30.6%) events. This was followed by digestive adverse drug reactions: 14/49 (28.6%); neurological adverse drug reactions: 11/49 (22.5%); pulmonary adverse drug reactions: 3/49 (6.1%); cardiovascular adverse drug reactions: 2/49 (4.1%); and others: 4/49 (8.2%).		Low
Murie J 2003 ⁷⁰	Observational	General practice	UK	Significant Event Audit		Looked at 55 significant events: operational accounted for 24/55 (43.6%), followed by clinical 20/55 (36.4%); strategic failures: 9/55 (16.4%); human resources: 2/55 (3.6%); environmental: 3/55 (5.5%); political: 1/55 (1.8%) and legislative: 1/55 (1.8%).	Of the 55 cases reviewed, 12/55 (21.8%) resulted in death; 10/55 (18.2%) resulted in severe harm; 2/55 (3.6%) resulted in moderate harm; 5/55 (9.1%) resulted in low harm; and 26/55 (47.3%) resulted in no harm.	Moderate

First author	Study type	Setting	Country	Measurement method	Number of safety incidents	Type of safety incidents	Harm associated with incidents	Quality rating
Neville RG 1989 ⁷¹	Observational	General practice	UK	Review of prescriptions	There were a total of 504 incidents from 15,916 prescription items (3.17%) during a three month observation period at one clinic.	212/504 incidents (42.1%) related to dose. This was further broken down as: strength of preparation not stated: 162/212 (76.4%); dose wrong by multiple of 10: 4/212 (1.9%); and other incorrect dose: 46/212 (21.7%). 187/504 (37.1%) related to quantity (wrong pack size). 40/504 (7.9%) related to naming of drugs, further subcategorized as follow: incomplete description: 33/40 (82.5%); confusion of similar names: 3/40 (7.5%); wrong drug: 3/40 (7.5%); and controlled drug regulations not followed: 1/40 (2.5%). 57/504 (11.3%) of the prescription incidents related to formulation. 8/504 (1.6%) related to 'limited list (prep not available on NHS)'.		Low
Nicholson D 2006 ⁷²	Observational	Primary care	USA	Record review	Of the 24 participating physicians, 22/24 (91.7%) made at least one prescribing incident over the seven month period that led to an adverse event. All of the incidents leading to an adverse event were described as preventable or ameliorable.			Low
O'beirne M, 2013 ⁷³	Observational	Family practice	Canada	Incident reporting system		264 incident reports were submitted by 191 practices. The top four types of incidents reported were documentation (41.4%), medication (29.7%), clinical administration (18.7%) and clinical process (17.5%).	Most reported incidents were judged to have 'virtually certain evidence of preventability' (93%). Harm was associated with 50% of incidents. Only 1% of the incidents had a severe impact.	Moderate

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Olaniyan JO 2014 ⁷⁴	Systematic review	Primary care	UK	Various	Thirty-three studies estimating the incidence of medication incidents in primary care were identified and thirty-six studies evaluated the impact of incident-prevention interventions. Medication incidents were found to be common, with incident rates ranging from less than 1% to more than 90%, depending on the definitions and methods used.	The prescribing stage was most susceptible to incidents. Those aged over 65 years and children were more likely to experience significant incidents.		High
Paille F 1995 ⁷⁵	Observational	General practice	France	Review of prescriptions	Focused on incidents for people with hypertension. Found that 1324/4080 (32.5%) prescriptions contained potentially inappropriate medications.			Low
Pandit NB 2008 ⁷⁶	Observational	Primary care	India	Survey	Reviewed 182 organizations. 77% of had unsafe injection practices, including the use of a boiling pan for sterilisation, recapping of needles and exposure to body fluids. The prevalence of needle stick injuries among service providers was 52.2% and the annual incidence of needle stick injuries was 19%.			Low
Pariser RJ 1987 ⁷⁷	Observational	Primary care	USA	Record review		Reviewed 319 medical incidents in 260 patients with skin conditions. 281/319 (88.0%) were diagnosis incidents.		Low
Pearson A 2009 ⁷⁸	Systematic review	Primary care	Australia	Various		Incidents related to administration, knowledge and skills, prescribing, processes and communication.	Review of 33 studies found that harm rates ranged from 24% to 42%.	High

First author	Study type	Setting	Country	Measurement method	Number of safety incidents	Type of safety incidents	Harm associated with incidents	Quality rating
Phillips Jr RL 2004 ⁷⁹	Observational	Primary care clinic	USA	Malpractice claims			26,126 peer-reviewed malpractice claims were reviewed. 5921/26126 (22.7%) were assessed as negligent claims. The malpractice claims data identified the following levels of harm to patients. 2148/5921 (36.3%) resulted in a death; 1124/5921 (19.0%) resulted in severe harm; 1542/5921 (26.0%) resulted in moderate harm; and 1107/5921 (18.7%) resulted in low harm.	Moderate
Phillips RL 2006 ⁸⁰	Observational	Family medicine clinics	USA	Incident reporting system		Examined reports to primary care incident report system. 898/935 (96.0%) were process incidents and 37/935 (4.0%) were knowledge and skill incidents.	145 / 701 (20.7%) incidents resulted in no harm to the patient, 196/701 (30.0%) in low harm, 203/701 (30.0%) in moderate harm, 100/701 (14.3%) in severe harm and 57 / 701 (8.1%) in death.	High
Rosser W 2005 ⁸¹	Observational	Family medicine clinics	Canada, England, Netherlands, New Zealand, USA, Australia	Incident reporting system		Examined 508 incident reports. The most common cause of incident was classified as office processes: 160/508 (31.5%). This was followed by: treatment incidents: 109/508 (21.5%); clinical knowledge: 89/508 (17.5%); external investigations: 73/508 (14.4%); communication: 62/508 (12.2%); work force management: 10/508 (2.0%); and financial accounting: 5/508 (1.0%).		High

First author	Study type	Setting	Country	Measurement method	Number of safety incidents	Type of safety incidents	Harm associated with incidents	Quality rating
Rubin G 2003 ⁸²	Observational	General practice	UK	Incident reporting system		Examined 940 incident reports. These were subcategorized as follows: prescription incidents: 397/940 (42.2%); communication incidents: 282/940 (30.0%); equipment incidents: 153/940 (16.3%); appointments incidents: 63/940 (6.7%); clinical incidents: 24/940 (2.6%); other incidents: 21/940 (2.2%).		Low
Ryan C 2009 ⁸³	Observational	General practice	Ireland	Record review	Records of 500 elderly people were screened. One tool found 69 medicines were prescribed inappropriately in 65 patients (13%). Another tool identified 63 potentially inappropriate medicines in 52 patients (10.4%).			Moderate
Sandars J 2003 ⁸⁴	Systematic review	Primary care	UK	Various	Review of 280 studies found wide differences in rates of incidents in primary care, varying from five to 80 per 100,000 consultations. Prescribing and prescription incidents have been found to occur in up to 11% of all prescriptions, mainly related to incidents in dose.	Incidents related to diagnosis were the most common across all studies, varying from 26% to 78% of identified incidents. Incidents associated with diagnosis, either delayed or missed, were most likely to result in major harm.		High

First author	Study type	Setting	Country	Measurement method	Number of safety incidents	Type of safety incidents	Harm associated with incidents	Quality rating
Sayers YM 2009 ⁸⁵	Observational	General practice	Ireland	Review of prescriptions	From a total of 3,948 prescriptions, 491 (12.4%) contained one or more incidents. From a total of 8,686 drug items, 546 (6.2%) contained one or more incidents.	The most common incident was 'no direction': 226/491 (46.0%), followed by 'other prescription-related cause': 93/491 (18.9%). The rest of the breakdown was as follows: not dated: 71/491 (14.46%); inadequate information: 60/491 (12.2%); mix up of prescriptions: 51/491 (10.4%); wrong dose: 43/491 (8.8%); no age given: 37/491 (7.5%); CD incident: 27/491 (5.5%); illegible: 27/491 (5.5%); off market: 20/491 (4.1%); not signed: 17/491 (3.5%).		Low
Schiff GD 2013 ⁸⁶	Observational	Primary care	USA	Malpractice claims		Examined 551 malpractice claims from primary care. Allegations were related to diagnosis (72.1%), medications (12.3%), other medical treatment (7.4%), communication (2.7%), patient rights (2.0%), and patient safety or security (1.5%).		Low
Schneider JK 1992 ⁸⁷	Observational	General medicine	USA	Record review	Records for 332 elderly people who attended a general medical clinic and 131 who attended a geriatric clinic showed potential drug interactions in 143 people (31%). There were 107 documented adverse drug reactions in 97 patients (21%). Of these patients, 86 were noted by doctors as having had a reaction.		Twelve reactions led to hospitalization.	Moderate
Schweppach DL 2012 ⁸⁸	Observational	Primary care	Switzerland	Survey		630 doctors and nurses were surveyed and 391 (31%) described 936 threats to patient safety. Safety of medication (8.8%), triage by nurses (7.2%) and drug interactions (6.8%) were the threats cited most frequently.		Low

First author	Study type	Setting	Country	Measurement method	Number of safety incidents	Type of safety incidents	Harm associated with incidents	Quality rating
Shaughnessy AF 1989 ⁸⁹	Observational	Family practice	USA	Review of prescriptions		1814 prescriptions by family medicine residents were reviewed and incidents were categorized as: omissions: 707/1814 (38.97%); incorrect dosage: 254/1814 (14.00%); legal issues: 109/1814 (6.01%); non-prescription based: 417/1814 (22.99%); inaccurate/vague quantity: 218/1814 (12.02%); and incomplete direction: 109/1814 (6.01%).		Moderate
Singh H 2013 ⁹⁰	Observational	Primary care clinic	USA	Record review		Reviewed 190 diagnostic incidents identified at two primary care facilities. Found missed diagnoses in 68 cases, relating to pneumonia (6.7%), decompensated congestive heart failure (5.7%), acute renal failure (5.3%), cancer (5.3%), and urinary tract infection or pyelonephritis (4.8%). These were due to issues in one or more of the following: the clinical encounter (78.9%), referrals (19.5%), patient-related factors (16.3%), follow-up (14.7%), and diagnostic tests (13.7%).	86% of incidents were classed as potentially moderately or severely harmful.	Moderate
Smith PC 2005 ⁹¹	Observational	Primary care	USA	Survey	253 clinicians were surveyed about 1614 patient visits. Clinicians reported missing clinical information in 13.6% of visits.	Missing information included laboratory results (6.1% of all visits), letters/dictation (5.4%), radiology results (3.8%), history and physical examination (3.7%), and medications (3.2%).		Moderate

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Smits M 2010 ⁹²	Observational	Family practice	Netherlands	Record review	145 patient records were reviewed and 27/145 (18.6%) patient safety incidents were identified.	15/27 incidents (55.6%) related to inadequate or suboptimal treatment; 9/27 (33.3%) related to triage incidents; and 6 /27 (22.2%) related to wrong or misguided diagnosis.	Of the 27 identified patient safety incidents, 8/27 (29.6%) had consequences for patients: an extra intervention was needed in 6/27 (22.2%) cases, and 2/27 (7.4%) patients had to be admitted to a hospital. No incidents resulted in permanent harm or death.	Moderate
Statham MO 2008 ⁹³	Observational	General practice	Australia	Record review			1062 people with acute eye disease were assessed. Incorrect diagnoses accounted for 642/1062 (60.5%) patients. conditions that were misdiagnosed and subsequently associated with severe adverse patient outcome occurred in 91/123 (74.0%) patients. The remainder had a correct initial diagnosis, but subsequent incorrect treatment: 32/123 (26.0%). 63/123 (51.2%) suffered low harm; 49/123 (39.8%) suffered moderate harm; and 11/123 (8.9%) suffered severe harm. There were judged to be 123/1062 (11.6%) patients who suffered preventable adverse outcomes.	Moderate

First author	Study type	Setting	Country	Measurement method	Number of safety incidents	Type of safety incidents	Harm associated with incidents	Quality rating
Stewart L, 2012 ⁹⁴	Observational	Primary care clinic	USA	Interviews		Of 219 patients interviewed to compare their medication use with their medical record, 162 (74%) had at least one discrepancy. The most common type of discrepancy was an incorrect medication documented on the chart. The most common reasons included over-the-counter (OTC) use of medications and patients not reporting use of medications.		Low
Straand J 1999 ⁹⁵	Observational	General practice	Norway	Review of prescriptions	Reviewed 16774 prescription incidents among elderly people. 13.5% of prescriptions met criteria for inappropriate prescribing.			Moderate
Tam KWT 2008 ⁹⁶	Observational	Primary care	Hong Kong	Record review and incident reports		Of the 132 adverse drug events in four clinics, 108/132 (81.82%) were categorized as actual adverse drug events (as opposed to potential adverse drug events). Of these, 5/108 (4.6%) were preventable; and 103/108 (95.4%) were non-preventable. Of the 108 adverse drug events, 5/108 (4.6%) were detected as preventable.		Moderate

First author	Study type	Setting	Country	Measurement method	Number of safety incidents	Type of safety incidents	Harm associated with incidents	Quality rating
Taylor LK 2005 ¹⁰⁷	Observational	Primary care clinic	USA	Incident reporting system		Looked at alerts generated by prescriptions over a nine-month period, and found alerts for prescription incidents in 6428/22419 (28.7%) cases. These were subcategorized as: drug-disease contraindication : 2644/6428 (41.1%); drug-drug interactions: 1522/6428 (23.7%); potential toxicity: 1022/6428 (16.0%); drug duplication: 731/6428 (11.4%); contraindicated for patient age: 249/6428 (3.9%); potential dosing incident: 221/6428 (3.4%); and other: 39/6428 (0.6%).		Low
Tilyard M 2005 ⁹⁷	Observational	General practice	Australia, Canada, Netherlands, New Zealand, UK, USA	Incident reporting system		431 incident reports which were categorized as: treatment process incident: 110/431 (25.5%); office administration incident: 82/431 (19.0%); investigation process incident: 73/431 (16.9%); communication incidents: 62/431 (14.4%); wrong diagnosis: 54/431 (12.5%); and other: 50/431(11.6%).		Moderate
Tomlin A, 2012 ⁹⁸	Observational	General practice	New Zealand	Record review	During a 6-year period, 173,478 patients from 30 practices received 4,811,561 prescriptions. There were 37,397 allergies, adverse events and other warnings recorded for 24994 patients (14%).			Moderate

First author	Study type	Setting	Country	Measurement method	Number of safety incidents	Type of safety incidents	Harm associated with incidents	Quality rating
Tsang C 2012 ⁹⁹	Systematic review	Primary care	UK	Various	Review of 15 studies of the types of adverse events that are routinely recorded in primary care found about 6.5% of adult emergency admissions were due to drug-related events. Between 0.7% and 2.3% of deaths following adverse events were attributed to treatment in primary care. In patients aged >65 years, the occurrence of adverse drug events was estimated at 4.9 per 1000 population			High
Tsang C 2013 ¹⁰⁰	Observational	General practice	UK	Record review	Examined 74,763 people's records. Incidence was 6 adverse events per 1000 person-years (95% CI 5.74 to 6.27), which is equivalent to 8 adverse events per 10,000 consultations. Those at greatest risk were patients aged 65-84 years, those with the most consultations, five or more emergency admissions, and those with the greatest number of conditions. People registered at their practice for the longest periods of time had a lower risk of an adverse event.			Moderate

First author	Study type	Setting	Country	Measurement method	Number of safety incidents	Type of safety incidents	Harm associated with incidents	Quality rating
Tse J, 2011 ¹⁰¹	Observational	General practice	Australia	Record review		33 patient records were reviewed. High levels of accuracy were found in the area of demographic details (94%). Moderately high levels of accuracy were reported for allergies (61%) but also a considerable percentage of non-recorded information was present (36%). Inaccuracies in medication lists were reported in 51% of records reviewed with 32.1% of all medications being inaccurately recorded. While over 91% of participants had a history summary with eight or less items present, omissions were reported for one in every five participants.		Low
Van Der Hoof CS 2005 ¹⁰²	Observational	Primary care	Netherlands	Record review	Looked at the risk of inappropriate drug prescriptions. In the calendar year 2001, found the risk of receiving at least one inappropriate drug prescription in older adults was 5052/25258 (20%). Between 1997 and 2001, the 1-year risk of receiving at least one inappropriate drug prescription for older adults ranged between 16.8% (95% CI: 16.3–17.3%) and 18.5% (18.3–18.7%).			Moderate
Van Dulmen SA 2011 ¹⁰³	Observational	Primary care	Netherlands	Record review and incident reports	1000 records were reviewed from 20 practices. In 18 out of 1000 (1.8%; 95% CI 1.0 to 2.6) records an incident was detected.	The main causes of incidents were incidents in clinical decisions (89%), communication with other healthcare providers (67%), and monitoring (56%).		Moderate

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Wahls TL 2007 ¹⁰⁴	Observational	Primary care	USA	Survey	Diagnostic incidents associated with the failure to follow up on abnormal diagnostic studies ("missed results") are a potential cause of treatment delay. 106 clinicians were surveyed who saw an average of 86 patients per two week period. Providers encountered 64 patients with missed results during the two week period leading up to the study and 52 patients with treatment delays.	The most common missed results included imaging studies (29%), clinical laboratory (22%), anatomic pathology (9%), and other (40%). The most common diagnostic delays were cancer (34%), endocrine problems (26%), cardiac problems (16%), and others (24%).		Moderate
Wallace F 2013 ¹⁰⁵	Systematic review	Primary care	Ireland	Various		Examined the epidemiology of malpractice claims in primary care (written demands for compensation for medical injury). Studies reporting on original data with ten or more cases were eligible. Thirty-four studies were included. Twenty-eight studies included data from medical indemnity malpractice claims databases and six studies reported survey data. Fifteen studies were from the USA, nine from the UK, seven from Australia, two from France and one from Canada. Diagnosis incidents were the most common, accounting for 26% to 63% of all claims. Medication incident was the second most common, accounting for 5.6% to 20% of all claims.		Low

First author	Study type	Setting	Country	Measurement method	Number of safety incidents	Type of safety incidents	Harm associated with incidents	Quality rating
Weingart SN 2005 ¹⁰⁶	Observational	Primary care	USA	Record review and interviews	661 patients who received prescriptions from 4 primary care practices were interviewed and their records reviewed. Patients' failure to discuss 90 medication symptoms resulted in 19 (21%) ameliorable and 2 (2%) preventable adverse drug events. Physicians' failure to change therapy in 48 cases resulted in 31 (65%) ameliorable adverse drug events.			Moderate
Wetzels R 2009 ¹⁰⁷	Observational	General practice	Netherlands	Record review and incident reporting system		31 incidents were identified and classified as follows: Practice administration incidents accounted for 10/31 (32.3%). This was subcategorized as medical records: 7/10 (70.0%); appointments: 2/10 (20.0%); other – administration: 1/10 (10.0%). Diagnostic incidents accounted for 6/31 (19.4%). Broken down as: wrong diagnosis: 1/6 (16.7%); delayed diagnosis: 4/6 (66.7%); other diagnosis: 1/6 (16.7%). Therapeutic incidents accounted for 7/31 (22.6%). Subcategorized as: wrong, incomplete treatment: 5/7 (71.4%); other treatment: 2/7 (28.6%). Communication incidents accounted for 8/31 (25.8%). Subcategorized as: communication with patients: 3/8 (37.5%); and communication with caregivers: 5/8 (62.5%).		Moderate

First author	Study type	Setting	Country	Measurement method	Number of safety incidents	Type of safety incidents	Harm associated with incidents	Quality rating
Woolf SH 2004 ¹⁰⁸	Observational	Family medicine clinics	USA	Incident reporting system		Examined incident reports. Process incidents accounted for 135/184 (73.4%) of reports. Process incidents were further subcategorized as follows: treatment: 50/135 (37.0%); office administration: 33/135 (24.4%); investigations: 27/135 (20.0%); communication: 23/135 (17.0%); and insurance-related incidents: 2/135 (1.5%). Knowledge and skill incidents accounted for 49/184 (26.6%) of incident reports. These were further broken down into the below categories: execution of a clinical task: 6/49 (12.2%); wrong diagnosis: 26/49 (53.0%); and wrong treatment decision: 17/49(34.7%).		High
Zavaleta-Bustos M 2008 ¹⁰⁹	Observational	Primary care clinic	Mexico	Review of prescriptions		Reviewed 370 prescriptions. The most common incident was found to be inappropriate prescriptions: 268/370 (72.4%). This was followed by inappropriate dosage regime: 102/268 (38.1%); inappropriate indication: 92/268 (34.3%); unnecessary medications: 24/268 (9.0%); medication duplicity: 14/268 (5.2%); potential drug-drug interactions: 23/268 (8.6%); missing medication: 8/268 (3.0%); and inappropriate administration route: 5/268 (1.9%).		Moderate

Additional material included in systematic reviews so not duplicated in the review

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Online content

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- Full protocol:
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