Appendix: Table 3: Studies measuring patient safety events in primary care settings identified in the literature

Systematic Literature Reviews					
Study	**Research aim**	**Research methods**	**Research measures**	**Design limitations**	**Overall conclusions**
Elder and Dovey (2002)[29]	Describe and classify process errors and preventable adverse events	Searches of Medline and the Cochrane Library	Preventable adverse events (diagnostic, treatment, preventive care incidents); Process errors (clinician, communication, administration, "blunt end" factors)	English language only	Little is known about primary patient safety in care. Most studies focus on physician perspectives.
Sandars and Esmail (2003)[33]	Identify frequency and nature of error in primary care; consider causes for diversity in reported error rates	Searches of Medline, Embase and NPSF database	5-80 "medical errors" per 100,000 consultations: 26-78% of "errors" relate to diagnosis 11-42% of "errors" relate to treatment <1-11% of prescriptions have "errors" 60-83% of "errors" are preventable	English language only	Nature and frequency of "error" in primary care is poorly understood because of diversity in definitions and approaches.
Baker et al (2007) [26]	Review how mortality data are used in primary care	Searches of Medline, Embase and CINAHL	Impact of primary care on mortality, methods of monitoring mortality, role of audit and death registers in quality and safety improvement.	English language only	Mortality data are not used systematically in primary care to improve quality and safety.
Studies of Significant Event Audits					
Murie and McGhee (2003)[31]	Describe significant events	Content analysis of 56 significant event reports from one Scottish Primary Care Trust	Ratio of near-miss to adverse events = 1:6 44% of reports relate to operational risk 36% of reports relate to clinical risk 16% of reports relate to strategic risk 4% of reports relate to human resources 2% of reports relate to political incidents 2% of reports relate to legislative incidents 56% had no or minimal harm 40% resulted in a disabling injury or death	Regionally limited	General practitioners can work in a national framework for risk assessment. There is a need for consistency in definitions and coding.
Bowie et al (2005)[27]	Identify satisfactory and unsatisfactory significant event reports	Content analysis of 662 significant event reports from the west of Scotland	25% involved a learning issue 11% of reports were judged unsatisfactory 17% of reports relate to prescribing 16% of reports relate to diagnosis 13% of reports relate to communication	Regionally limited	If significant event reporting is to be effective in improving quality and safety, there must be a valid way to check reports.
Cox and Holden (2007)[28]	Describe significant events	Content analysis of 337 significant event reports from one English Primary Care Trust	19% of reports involved a learning issue 29% of reports relate to prescribing 27% of reports were patient safety incidents 7% were serious or life-threatening 20% were potentially serious	Regionally limited	Significant event audits valuable for education and clinical governance that highlight patient safety issues.

Studies of malpractice claims and risk management databases					
Fischer et al (1997)[30]	Describe the prevalence of adverse events	Review of 51 incident reports to a risk-management database over .55 year period	3.7 "adverse events" per 100,000 clinic visits 14% of injuries due to environmental hazard 69% of injuries due to medical mismanagement: 31% relate to treatment 26% relate to diagnosis	Regionally limited Limited to an academic health center	Serious adverse events are probably infrequent in primary care. Better systems are needed to track events.
Phillips et al (2004)[32]	Describe negligent adverse events from primary care; assess condition-specific rates of claims	Review of 49,345 claims in a national US malpractice database over a 15 year period	68% of claims were for negligent events in primary care 34% of negligent claims relate to diagnosis 16% of negligent claims relate to failure to monitor 15% of negligent claims relate to improper performance 8% of negligent claims relate to prescribing 4% of negligent claims relate to delay in referral	Data definitions may not be robust Limited to the US	The total burden of high severity outcomes and death is higher when negligent events occur in primary care than when they occur in hospitals.
Varga et al (2006) [34]	Describe criminal liability of healthcare providers in Hungary	Review of 94 criminal cases involving physicians and other healthcare providers, over a 4 year period	82% of criminal cases involved physicians 29% of physicians were primary care physicians and the main reason for their case was failing to examine the patient or diagnostic error 10% of criminal cases involved nurses 5% of criminal cases involved paramedics 3% of criminal cases involved pharmacists	Limited to Hungary	Primary care physicians are at the centre of more criminal cases than any other healthcare professional group.
Interview studies					
Diamond et al (1995)[38]	Describe GP trainee experiences with positive and negative incidents	Qualitative analysis of open-ended interviews with 39 GP trainees	180 critical incidents (4.6 per doctor) 50% of critical incidents involved difficult patients, children, counseling skills, the doctor-patient relationship, obstetrics and gynaecology, relationships with other health professionals and practice staff, and cardiovascular disorders.	Purposive sampling from one training program	Analysis of critical incidents can accelerate learning and help plan curricula.
Ely et al (1995)[44]	Determine perceived causes of family physician error	In-depth interviews with a random sample of 70 family physicians	76% response rate (53 physicians/errors) 57% of errors related to missed diagnosis 21% of errors related to surgical mishaps 25% of errors related to treatment Mean of 8 causes for each error case 91% of errors caused by physician stressors 91% of errors caused by care processes 72% of errors caused by patient factors 62% of errors caused by physician factors	No sample size justification	Physicians remembered errors with often serious consequences that they attributed to a variety of causes.
Kuzel et al	Develop patient-	Structured interviews	38 interviews analysed	No sample size	Medical errors related by

(2004)[51]	focused typologies of medical errors and harms in primary care	with 40 people recruited by random digit dialling	Mean of 5.8 problematic incidents per interview 37% of incidents involved breakdown in doctor-patient relationship 77% involved disrespect or insensitivity 29% of incidents involved breakdown in access 27% involved excessive office waiting times 16% involved difficulty in contacting the office 16% involved delay in obtaining appointments Mean of 4.5 harms per interview (170 harms) 70% of harms were psychological	justification	patients contrast sharply with errors reported by family physicians.
Avery et al (2006)[35]	Define ways computer systems can be improved to enhance safety in primary care	Semi-structured interviews with 31 clinicians, computer system suppliers, academics, and policymakers	4 main themes Designing systems for safety Accurate and relevant information Taking human ergonomics into account Audit trails Electronic information transfer Optimizing computer safety features Recording data accurately Call and recall reminders Training for safe and effective computer use Regulations and guidelines Safety culture	Limited to stakeholders with computer expertise Excluded non-medical team members and patients	Primary care computer systems could be improved and this would enhance patient safety.
Focus group studies					
Dowell et al (2005)[43]	Describe patients' experiences of quality and safety in primary care	3 focus groups including 21 patients from 3 urban clinics	187 comments 44% of comments were about system issues 37% of comments were about interpersonal skills 9% of comments were about knowledge 7% of comments were about medication and technical errors and errors of inattention	Limited to English language-proficient patients	Patients provide important insights into complex systems issues.
Mazor et al (2005)[55]	Describe how and why preceptors respond to trainees when medical errors occur	7 focus groups involving 38 primary care preceptors from north-west USA	Preceptors provided corrective and supportive responses to trainees' errors Factors influencing preceptors' responses were error type, clinical outcome, and their connection, and the learner's response	Analysis may be influenced by researcher bias	Future research should focus on faculty development to optimize learning from errors and reduce future recurrence
Surveys					
Holden et al (1998)[46]	Determine pattern of deaths and preventable factors in 4 general practices	Audit of all 1263 deaths occurring over 40 months, using a standard data collection form	679 avoidable factors contributed to deaths 40% were patient factors (eg smoking, suicide) 6% were hospital factors (eg delayed diagnosis) 5% were GP factors (eg delayed referral) 3% were environmental factors (eg falls)	Limited practice participation	An audit of deaths has educational value for GPs and is a source of ideas for service improvement and further study.

MacPherson et al (2001) [52]	Describe the type and frequency of adverse events and transient reactions after consultations with acupuncturists	Postal survey of 1848 professional acupuncturists	31% response rate (574) 34,407 treatment reports No serious adverse events 1.3 significant minor adverse events per 1000 treatments (eg nausea, fainting) 15% of treatments had mild transient reactions 3 avoidable errors (2 forgotten needles, 1 moxibustion burn)	Low response rate Non-random sampling	Acupuncture is a relatively safe treatment.
McKay et al (2004)[56]	Describe GPs' attitudes to mandatory significant event reporting	Census of 617 GP principals in south-west Scotland	76% response rate 73% would not report all significant events 75% favoured anonymous reporting 41% had difficulty defining a significant event	Non-random sampling	The success of the NPSA system will be hindered by mandatory reporting.
Singh et al (2005)[62]	Develop and test a method to form learning teams that can prioritize patient safety problems	2 practices with 45 respondents	Each site identified its own hazards, with little overlap	No denominator reported Non-random sampling	The method empowered practice teams to develop a common vision of their practice microcosm.
Hutchison et al (2006)[47]	Develop a patient safety climate questionnaire (the MaPSaF)	Census of 3650 staff of 4 acute hospital trusts and 9 primary care trusts in England. Factor and reliability analyses	Response rate 33% for primary care Trusts Removing 5 items from the questionnaire improved the internal reliability of the questionnaire's two domains of teamwork and safety climate	Low response rate Non-random sampling	A 22-item version of the questionnaire is usable as a research instrument in primary care and acute hospital settings.
Patient Safety Event Reporting Systems					
Britt et al[37] Bhasale et al[36] (1997-98)	Describe safety incidents in General Practice	Modified critical incident technique, with 297-324 GPs anonymously submitting 500-805 paper incident reports	51-52/100 mishaps involved drug treatments 37-42/100 mishaps involved non-drug treatments 28-34/100 mishaps involved diagnosis 5/100 mishaps involved equipment 76 % of incidents were preventable 17% of incidents resulted in major harm 4% of incidents resulted in death Poor communication was the most common contributing factor Early intervention was the most common mitigating factor	Participation limited to one sentinel practice research network and additional volunteers	The incident monitoring technique can be used in general practice.
Dovey et al[39-42] (2002-03)	Describe the types of errors reported	344-416 errors reported by 42 family	31% were reports of administrative errors 25% were reports of investigation failures	Participation limited to one	Family physicians will report errors and their

	by family physicians and develop an error taxonomy	physicians using both paper and computer based questionnaires	23% were reports of treatment errors 6% were reports of communication errors 337 reports of consequences 38% were health consequences 35% were care consequences 22% were financial and time consequences 288 ideas about solutions to medical errors 34% of solutions were "don't make mistakes" 30% of solutions were "better communication" 26% of solutions were "provide care differently"	sentinel practice research network	consequences and propose solutions.
Makeham et al,[53] Woolf et al,[68] Rosser et al,[59] Jacobs et al,[48] Tilyard et al[64] (2002-05) The PCISME project	To describe the types of errors reported by GPs and family physicians in 7 countries and develop an international error taxonomy	Paper and computer based questionnaires submitted by 100 GPs and family physicians over a four month period	437 error reports: 132 from Australia, 81 from Canada, 63 from England, 14 from Holland, 66 from New Zealand, 75 from the US. 9-25% of reports related to office processes 14-30% of reports related to treatment 14-22% of reports related to investigations 7-19% of reports related to communication 2-3% of reports related to workforce 1-2% of reports related to finances 77% of reports documented a chain of errors 29-39% of reported incidents resulted in harm 66 different prevention strategies 70% of reports related to more diligence 23% of reports related to providing care differently 20% of reports related to communication	Small number of reports per country Limited time frame for data collection	Errors are common and similar in nature in general practice and family medicine settings around the world.
Wilf-Miron et al (2003) [66]	Apply aviation safety principles to reporting errors in a large ambulatory healthcare setting	Root cause analysis of 2000 adverse event reports over 5 years reported by telephone hotline to a specialized risk management unit	1300 events were accidents and near misses 21% involved family medicine 33% of errors related to processes of care 21% of errors related to treatment 18% of errors related to judgment 15% of errors related to auxiliary tests 13% of errors related to poor communication 470 recommendations made to improve care	Regionally limited Multidisciplinary study did not report primary care results separately	Aviation safety concepts and tools were successfully adapted to ambulatory care.
Fernald et al,[45] Parnes et al,[57] Westfall et al[65] (2003-04) The ASIPS	Develop a system for confidential error reporting, describe types of error and differences	128-754 confidential or anonymous reports submitted by phone, electronically, or on paper from 14-33 practices with 150-	97- reports of patient safety events 71-72% of reports involved communication 33% of reports involved delay in care 20-35% of reports involved medication events 17-47% of reports involved diagnostic testing 209 reports of harm from patient safety events	Participation limited to two sentinel practice research networks Regionally	Confidential reports afford greater analysis of cause than anonymous reports.

project	between confidential and anonymous reports	475 clinicians and staff	68% were no known harm 6% were unstable 7% were non-clinical harm 9% were increased risk of clinical harm 10% were clinical harm now	limited	
Rubin et al,[60] Steele et al[63] (2003-06)	Classify errors in general practice and community optometric clinics in north-east England	540 events reported using an anonymous paper form, reporters coded events using a descriptive classification	136 reports of 940 errors from general practice and 439 from optometric practice 18-42% of errors related to prescriptions 30-36% of errors related to communication 12-16% of errors related to equipment 2-7% of errors related to appointments 10-35% of errors related to clinical care 75.6 “errors” per 1000 GP consultations	Regionally limited Limited time frame for data collection	Medical error descriptions generated in primary care are applicable to different types of provider.
Shaw et al (2005)[61]	Describe the implementation of a national incident reporting system	Electronic patient safety incident reports from 1 Primary Care and 17 other Trusts in England and Wales	28,988 safety incident reports were made 32 (0.1%) came from the primary care Trust	No data reported for primary care specifically	Majority of reported incidents from all sources were slips, trips and falls. Primary care engages poorly in the system.
Makeham et al (2006)[54]	Determine the incidence of reported errors in general practice	418 anonymous web-based error reports from a random sample of 320 New South Wales (Australia) GPs over 12 months	26% (84) of the random sample of 320 agreed to participate in the study 1-25 reports per participating GP 5.3 reports on average, per participating GP 1 error per 1000 GP encounters per year 2 errors per 1000 patients seen per year Incidence of reported errors per patient = 0.24%	Regionally limited Low response rate	Incidence of GP-reported errors can be calculated when a secure anonymous reporting system is provided.
Phillips et al (2006)[58]	Compare the types of medical error reports made by primary care clinicians, administrative staff, and patients.	126 reports from patients and 717 reports from 401 clinicians and staff reporting electronically, in paper reports, or by telephone.	108/126 patient reports expressed satisfaction 6/18 patient error reports were about waiting 2/18 patient error reports were about mistaken identity 717/726 provider reports included 935 errors 56% of errors related to office administration 15% of errors related to treatments 14% of errors related to investigations 9% of errors related to communication 4% of errors related to knowledge and skills 3% of errors related to payment	Study design unsuitable for learning of patients’ views of patient safety	Clinicians and administrative staff perceived errors differently (through different “lenses”). Patients did not engage well with the study’s processes.
Kostopoulou (2007)[50]	Describe patient safety incidents in general practice based on cognitive psychological	78 reports from 5 general practices with follow up interviews from investigators	21 adverse events and 50 near misses 47 reports had information about the active failure leading to the patient safety incident 45% involved situation assessment errors 23% involved response execution errors	Small number of reports limits description breadth	Cognitive and system factors both contribute to patient safety incidents in primary care.

	theory		17% involved memory errors 15% involved perception errors 17% had fairly or very serious patient harm 76% had potential for patient harm		
Mixed Method studies					
Elder et al (2004)[71]	Describe errors identified by family physicians and determine physician's perception of resulting harm	15 family physicians in 17 practices identified errors during 351 patient visits. Interviews at the end of consulting sessions collected data about harm.	117 errors reported in 83 (24%) consultations 17% of error visits were administration error 8% of error visits were physician related error 5% of error visits were communication error 45% of error visits were preventable adverse events 24% of error visits harmed patients 70% of error consultations involved potential harm	Regionally limited	There is variation between doctors in how harm is defined and how different error categories are interpreted.
Dean et al (2007)[69]	Evaluate feasibility of prospective hazard analysis of care pathways crossing primary and secondary care interface	Observation of care processes for patients with COPD, interviews with 16 patients and 7 staff, two-round modified Delphi study	Themes from interviews were mainly about communication problems The Delphi study ranked difficulties in accessing hospital records, information transfer to primary care, and failure to communicate medication changes as the most important events	Limited to one chronic disease	Mixed methods study delivered a clear picture of the quality and safety of care in a care pathway.
Elder et al (2006) [70]	Define what physicians consider an "error"	Systematic review followed by census of active members of the American Academy of Family Physicians	25 different definitions of "error" found in the literature The most common definition is Reason's[9] 29% response rate to the survey Family physicians' definition of error depends on event outcomes, whether the event was rare or common, and whether it was related to the system of care or an individual mistake.	English language literature only Low response rate to survey Survey sample size not justified	Definition of "error" is an area of confusion
Kaldjian et al (2006) [72]	Describe factors affecting voluntary disclosure of medical errors by physicians	Literature review; 5 focus groups	Literature review revealed 53 factors impeding disclosure and 38 factors facilitating disclosure Focus groups added 27 factors The final taxonomy had 4 facilitating factors: Responsibility to patient; Responsibility to profession; Responsibility to self; Responsibility to community and 4 factors impeding error disclosure: Attitudinal barriers; Helplessness; Uncertainty; Fears and anxieties	English language literature only MEDLINE database search only	A conceptual framework describing factors facilitating and impeding disclosure of medical errors was developed.
Kirk et al	Test a framework	Literature review,	9 dimensions of organization safety culture were:	Regionally	Provides a way of

(2007)[73]	for making the concept of a safety culture meaningful to primary care providers	survey,33 semi-structured interviews, 14 focus groups	Overall commitment to quality; priority given to patient safety; perceiving the causes of patient safety incidents; investigating patient safety incidents; organizational learning following a patient safety incident; communication about patient safety; personnel management; staff education; team-working 5 levels of safety culture maturity were: Pathological; reactive; calculative; proactive; generative	limited	understanding why and how the shared values of staff can together create a safety culture in practice
Wallace et al (2007)[74]	To examine the effect on practice safety culture of a health authority's promotion of risk management	Survey of 75 practice managers to derive a risk management competence score before and after an intervention of a training package to improve risk management skills	Risk management competence scores of practices after the intervention did not change significantly from before. 6 general measures of competence: Scope: before = 11, after = 13 Staff involved in risk management: before = 12, after = 15 Documenting risk management activity: before = 6, after = 13 Access to records: before = 15, after = 15 Written practice policies: before=9, after=11 Written procedures: before = 8, after = 8	Non-random sample Before-and-after study without controls	There was evidence that risk management improved over the period of the study but little evidence that this was caused by organizational culture