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Evidence Check

Patient characteristics and interventions associated with complaints and medico-legal claims

An Evidence Check rapid review brokered by the Sax Institute
for Avant Insurance Limited—November 2022

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This report was prepared by: Timothy J Schultz, Michael Zhou, Jodi Gray, Jackie Roseleur, Richard Clark, Dylan A Mordaunt and Peter Hibbert, Flinders University.

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Executive summary

Background

Claims seeking compensation for medical negligence may be filed against doctors by patients through civil litigation. For less serious events or to express dissatisfaction with care, patients may also complain, either directly to their care provider or the provider's employer, or to medical and other regulators and health complaints entities.(1) Both claims and complaints are rich sources of information for quality improvement and can inform the development of strategies to reduce the likelihood of future events.

Anecdotal evidence suggests that the rate of complaints and claims is rising.(2) There is a large amount of research about the relationship between doctor's characteristics and complaints and claims against them.(1) It is less clear what, if any, patient characteristics are associated with complaints and claims.

Medical indemnity insurers and health services deliver risk management education and training to health practitioners to reduce complaints and claims. Other stakeholders such as medical colleges and practitioner regulation boards have responsibility for maintaining the professional standards of their members and conduct activities such as continuing professional development (CPD) (3) or remediation programs. (4) The effectiveness of recent programs and interventions on outcomes such as rates of claims against doctors'; patient satisfaction; and doctor satisfaction, confidence and performance is unknown.

Review questions

This review aimed to address the following specific questions:

Question 1: "What are the common characteristics and circumstances of patients who are most likely to complain or bring a claim about the care they have received from a doctor?"

Question 2: "What initiatives or interventions have been shown to be effective at reducing complaints *[and claims]* about the care patients have received from a doctor?"

Summary of methods

We searched three bibliographic databases (PubMed, Scopus and Web of Science) and a large number of grey literature sources for relevant studies. Over 8000 search results were screened against the inclusion criteria resulting in a total of 24 studies included for Question 1, 19 studies included for Question 2 and one study included for both questions. To ensure applicability to a modern Australian healthcare system, studies published recently (post 2011) in countries with similar health systems (New Zealand, United Kingdom and Canada) were prioritised for inclusion.

The quality and study design of the 44 included studies was appraised using National Health and Medical Research Council (NHRMC) guidelines, including a matrix to summarise consistency, clinical impact, generalisability, and applicability. Study designs that are not listed in NHMRC guidelines (for example, cross-sectional studies, or systematic reviews on non-randomised controlled trials) that were relevant to both review questions were included as 'other' study types. To support concepts for which little evidence was retrieved, high quality literature reviews (e.g. for which a search strategy was defined and, a study protocol was prospectively registered) were also included.

A narrative synthesis was used to describe the key findings for both review questions. For review Question 1, results are presented separately for 13 patient characteristics. For review Question 2, results are presented separately for seven types of interventions.

Key findings

The overall quality of the evidence was poor with about 60% of the included studies (n=26 of 44) not listed as study designs in NHMRC levels of evidence. Additionally, one-third of studies (n=13, 30%) were at the lowest of NHMRC's levels of evidence (level IV – Case series).

Question 1: What are the common characteristics and circumstances of patients who are most likely to complain or bring a claim about the care they have received from a doctor?

- The evidence base for Question 1 is poor. Of the 25 studies included in Question 1, 21 are best described as 'Other' study designs based on NHMRC levels of evidence categories, and these are mainly cross-sectional studies of complaints/claims that report the underlying characteristics of a claims database. Only four studies included a control group.
- There were 13 types of patient characteristics described in more than one study. The most frequently reported characteristics were: age (19 studies), sex (17 studies), patient risk factors (9 studies), therapeutic context (6 studies), complainant (6 studies), race (5 studies), and employment status (4 studies).
- Other than for patients with mental, behavioural and developmental disorders, no other patient characteristics demonstrated either a strong or consistent effect on the rate of complaints or malpractice litigation.
- The results suggest that higher patient age (within a given patient population) may be weakly correlated with a greater chance of a complaint and that female patients or female relatives of male patients were more likely to make complaints than male patients.

- There is little consistent evidence about relationships between patient risk factors, therapeutic context, and complainant status and the likelihood of a complaint or claim. While a number of studies have demonstrated family members or friends are more likely to complain than patients, a 2014 systematic review of 36 studies concluded otherwise, reporting that patients accounted for 64% of complaints and family members accounted for only 26%.
- There was no evidence of a relationship between race and rate of complaints or malpractice litigation.
- There was mixed evidence assessing the relationship between employment status and rate of complaints or malpractice litigation.
- In one study, underlying mental health conditions were associated with higher rates of patient complaints.
- There was little evidence for a relationship between other patient characteristics including length of hospital stay; complications; insurance status; marital status; education; relationship with clinician; and the rate of complaints or malpractice litigation. There were a few weak relationships noted:
  - shorter length of stay may be associated with higher likelihood of complaint.
  - insured patients or medical cardholders may be more likely to sue for malpractice
  - married or *defacto* patients may be less likely to complain or sue for malpractice than single patients.

Question 2: What initiatives or interventions have been shown to be effective at reducing complaints about the care patients have received from a doctor?

- The evidence base for Question 2 is poor. Of 20 studies included in Question 2, 18 are best described as either NHMRC level IV evidence, or 'Other' study designs. These study designs are at clear risk of bias and may therefore be more likely to erroneously demonstrate an effect.
- There were seven types of interventions described: risk management programs, communication and resolution programs, peer programs, continuing professional development (CPD), medical remediation programs, shared decision-making and simulation training. All these interventions target doctors, not patients. Evidence for each type of intervention is summarised here:
  - There was a consistent effect of reduced rates of claims and complaints following implementation of risk management programs. Reduced costs from malpractice claims, more timely responses and improved staff satisfaction, knowledge, confidence, perceptions of culture and preparedness for a claim were all reported.
  - There was a consistent effect in showing lower rates of claims and complaints, lower non-compensation and compensation claim costs, and faster resolution of claims following implementation of communication and resolution programs.
  - There was a consistent effect in improving doctors' response to, and performance following, complaints following implementation of peer programs providing feedback to doctors.
  - Two included studies provided evidence supporting an improvement in doctor performance and reduced rate of complaints about quality of care following CPD participation.
  - Two included studies demonstrated positive results from medical remediation programs in terms of improving performance to an acceptable standard and reducing number of events (claims, pre-claims, disciplinary and regulatory episodes).

- Two included studies, including a systematic review, provided only limited evidence supporting a proposition that shared decision making leads to fewer medico-legal claims or complaints.
- One included study provided evidence that simulation training leads to an approximate halving of malpractice claim rates.

Gaps in the evidence

For Review Question 1 there were only four case-controlled studies allowing comparative evaluation between the assessment group and a control. The many uncontrolled and unadjusted cross-sectional studies of complaints/claims that simply report the underlying characteristics of a claims database do not provide particularly useful insights into the relationship between patient characteristics and rates of complaints or claims.

For Review Question 2, the preponderance of lower quality study designs (case series) and absence of higher quality studies including randomised controlled trials is one of the largest gaps in the evidence. Given that there are multiple potentially effective interventions, and lack of clarity about which may be the most effective, a high quality study to compare effectiveness and costs of different approaches would be informative.

The Patient Advocacy Reporting System (PARS®) was used by three US studies to identify physicians at high risk of complaints.(5-7) Further research may determine the utility of a similar system developed for Australia.

Additionally, only one study was included that evaluated the effectiveness of medical regulation delivering medical remediation programs.(8) Given the significant resources involved in medical regulation, greater involvement in research and comparison of outcomes following medical regulation interventions is warranted.

The Evidence Check identified only one study that specified whether a complaint was warranted or unwarranted(9) and no study included both to allow determination of predictors of successful interventions targeting unwarranted claims/complaints.

Finally, a number of studies identified doctors participating in programs as ‘responders’ and ‘non-responders’.(6, 7) The small population of ‘non-responders’ deserves future investigation.

Conclusion

The overall quality of the evidence was poor with two-thirds of the included studies (n=26) not aligned with study designs included in the NHMRC levels of evidence. The majority of these studies (n=21) were relevant to Question 1 (Patient characteristics). Almost one-third of all included studies (n=13) were at the lowest level of NHMRC evidence (level IV – Case series); all of these were relevant to Question 2 (Interventions to reduce rates of complaints and/or claims). There was only one systematic review (level I evidence), this was relevant to Question 2.

Of 14 types of patient characteristics studied that may be related to the likelihood of making a complaint or initiating a malpractice claim, none demonstrated either strength or consistency of effect. Higher patient age (within a given patient population) may be weakly correlated with greater chance of complaint; female patients or female relatives of male patients may be more likely to make complaints than male patients. However, there are few, if any, patient characteristics that can be reliably considered to be related to the likelihood of medico-legal complaint or claims.

There was evidence for seven types of interventions targeting a reduction in claims and complaints against doctors that demonstrated reduced number and costs of claims, reduced number of complaints, and increased timeliness of claims/complaints management. However, the strength of the evidence is very weak. It is based on study designs that are highly prone to bias; lack control groups and statistical adjustment for confounders; have low sample sizes and/or are set in a single institution; and lack evidence about program fidelity and sustainability.

Background

Although healthcare practitioners do strive to achieve the best possible outcomes for patients, harm to patients is endemic within healthcare systems. It has been established that up to 10% of hospital patients experience an adverse event.(10) Medical negligence, or the failure to meet the standard of care reasonably expected of an 'average' doctor is a contributing factor in a small proportion of events in which patients are harmed as a result of their healthcare, either from an act of omission (failure to enact the correct treatment plan) or commission (improper execution of the correct plan).(10, 11) Claims seeking compensation for medical negligence may be filed against doctors by patients through civil litigation. For less serious events or to express dissatisfaction with care, patients may also complain, either directly to their care provider or the provider's employer, or to medical and other regulators and health complaints entities.(1)

In Australia, 15 national health practitioner boards work in partnership with the Australian Health Practitioner Regulation Agency (AHPRA), across professions guided by the Health Practitioner Regulation National Law (the National Law). The Medical Board of Australia falls under the aegis of AHPRA, with complaints handled by local boards in each state and territory. Claims and complaints against doctors need to be notified to their medical indemnity insurer under insurance contracts legislation and insurance policy requirements. Medical indemnity providers will provide support for the insured practitioner through the complaint or claim processes in accordance with the terms of their insurance policy.

Similar processes are in place in other countries with comparable health systems to Australia. In Canada, the medical regulatory authority is the College of Physicians and Surgeons, which collates complaints for research purposes. (9) There are some 500 written complaints to the UK National Health Service per day.(12) In New Zealand, complaints are managed by the Health and Disability Commissioner, however, this data is rarely subjected to empirical research.(13) Work at Vanderbilt University Medical Centre on the Patient Advocacy Reporting System® (PARS®) addressed this gap in the United States (US). The PARS tool helps to identify and address unprofessional behaviour and doctors at high risk of a complaint.(7, 14)

There is a relatively large amount of research about the relationship between doctors' characteristics and the complaints and claims against them. This has most recently been summarised in a systematic review of 67 peer reviewed studies published from 2011 to 2020.(1) It is less clear what, if any, patient characteristics are associated with complaints and claims, and anecdotal evidence suggests that the rate of complaints and claims is rising.(2) A 1999 Australian study found that 70% of complaints were by women, and 44% were on behalf of another person.(15) However, newer evidence is lacking. This led to Avant, an Australian provider of medical indemnity insurance, posing the following question, which was revised following feedback from the Sax Institute: "Question 1: What are the common characteristics and circumstances of patients who are most likely to complain or bring a claim about the care they have received from a doctor?"

As part of their core business, medical indemnity insurers such as Avant are highly incentivised to reduce the number of complaints and claims against their members. Hospitals and health services use complaints data to inform their safety and quality improvement activities and are similarly motivated to reduce complaints and claims against their staff. For example, it was recently revealed that the state of South Australia has settled medical malpractice claims for $100m over the last three years, and a further $300m may be required to settle claims currently in the system.(16) One way that both medical indemnity insurers and health services address their aim of reducing complaints and claims is to deliver risk management programs, comprising education and training to members/staff. Other stakeholders such as medical colleges and practitioner regulation boards are also responsible for maintaining professional standards of their members and conduct activities such as continuing professional development (CPD)(3) or remediation programs(4). The range of stakeholders and interventions that are potentially available to influence rates of complaints and claims, has led to the following question being posed by Avant: “Question 2: What initiatives or interventions have been shown to be effective at reducing complaints *[and claims]* about the care patients have received from a doctor?”.(2)

Purpose

The purpose of this review was to provide an evidence-based foundation to understand which patient factors influence complaints and what interventions can support a reduction in complaints, particularly in those instances where the care provided had not been below the expected standard and the complaint was not otherwise warranted.(2)

Scope of the review

The review has focussed on the Australian health system and countries with similar health systems (New Zealand, Canada and the United Kingdom (UK)). Additionally, in the absence of high level of evidence from such settings, studies from the United States (US), Ireland and Western Europe were included to inform the review.

The review focussed on the peer-reviewed literature. Grey literature of similar quality was also searched. The review was conducted over an eight-week period from September to October 2022.

Inclusion and exclusion criteria

The inclusion criteria and exclusion criteria for Question 1 and Question 2 are included in Table 1.

For Question 1, the review has flagged any correlation between the setting, type of care and patient characteristics and the type of complaint or nature of complaint.

For Question 2, the review has included interventions that have been studied or evaluated with experimental or quasi-experimental design (pre-post, control cohorts, randomised design).

Table 1 Summary of inclusion and exclusion criteria for the two review questions

	Inclusion criteria		Exclusion criteria	
	Q1	**Q2**	**Q1**	**Q2**
Setting	Inpatient, outpatient, primary care and secondary care settings		Emergency settings	
	Public and private practice settings		Nursing, allied health and ambulatory health workforce	
			Students and doctors in training	
Type of care	Chronic care management, acute episodic care, surgical and hospital interventions (including pre- and post-care)		-	
	Care with adverse or unexpected outcomes		-	
Types of complaints and claims	Claims for compensation (litigated and unlitigated)		Complaints on social media	
	Regulatory complaints (e.g. Australian Health Practitioner Regulation Agency (Ahpra), the Health Ombudsman (Qld), the Health Care Complaints Commission (NSW) or state/territory health complaints entities)			
	Complaints directly to a practice or hospital			
Characteristics: • **Patients (Q1)** • **Interventions (Q2)**	Demographics (age, gender, country-of-birth)	Changes to workflow or patient flow processes including consultation time, referral processes, wait times, or frequency of visits		
	Diagnosis	Changes to roles and responsibilities of care teams		
	Medical history	Education for doctors, including communication and risk mitigation strategies		
	Employment			
	Socio-economic status			
• **Circumstances (Q1)** • **Outcomes (Q2)**	Length and quality of relationship with doctor	Number of complaints/claims		

	Inclusion criteria		Exclusion criteria	
	Q1	**Q2**	**Q1**	**Q2**
	Length and complexity of episode of care	Patient satisfaction		
	Setting of care	Doctor satisfaction		
	Family involvement in care	Doctor confidence in being able to mitigate risks		

Methods

Peer reviewed literature

The search strategy is summarised in Appendix 1. The search of bibliographic databases for peer reviewed literature was modified from a recent, similar systematic review.(1) Given the aetiological nature of studies relevant to Question 1 in particular, we used a PEO approach (Participant, Exposure, Outcome) to frame the search strategy.(17) Terms relating to 'participants' included doctors and health services. Terms relating to 'exposure' included patient characteristics (such as demographics, socio-economic status, and health literacy) for Question 1, and patient safety interventions (such as checklists, care bundles and teamwork) or clinical risk management programs (such as medical education, risk mitigation) for Question 2. Terms relating to 'outcomes' included malpractice, negligence, complaint, claim management and medico-legal.

Three bibliographic databases (PubMed, Scopus and Web of Science) were searched. Medical Subject Heading (MESH) terms were used when relevant in PubMed. The search was conducted on 8 September 2022 and limited to publications since January 2011. The PubMed search identified 4,108 results, while the Scopus search identified 5,873 and the Web of Science search identified 11,431 results. These latter search results risked an unmanageable expansion of the screening therefore a location filter (corresponding to Australia, Canada, New Zealand, and the UK) was applied in Scopus and Web of Science. This reduced the search results from Scopus to 1,497 and for Web of Science to 2,397. Across the three databases 8,002 results were obtained.

Of these 8,002 results, 920 duplicates were identified and removed using Endnote. A filter was applied in online systematic review software Rayyan (18) (i.e. NOT "emergency department" in the title; NOT "nursing" in title in the absence of medical/doctor/physician) resulting in removal of 401 results. Of the remaining 6,681 results an additional 39 duplicates were identified and removed using Rayyan, leaving 6,642 results in the review.

A flowchart of the literature selection process is included as a PRISMA flowchart (19) in Appendix 2. Screening was conducted by four members of the research team following training on two sets of 100 studies. Of 6,642 search results, 6,469 were deemed not relevant to the review based on title and abstract. These were studies of incorrect study design (e.g. editorials, commentaries), or on the wrong topic (e.g. implementing patent safety interventions, clinician burnout, or defensive medicine).

There were 173 studies retrieved for full text review. Of these, 156 were excluded for the following reasons:

- Potentially relevant to Question 1 but a lower quality (ie lacking sufficient detail about patient characteristics or a control group), non-review set in the US or Western Europe (n=89)
- Potentially relevant to Question 2 but incorrect intervention type or study design and set in the US or Western Europe (n=8)
- Not relevant on full text review (n=24)

- A low quality or old literature review relating to Question 1 (n=5)
- A low quality literature review or summary of legal studies relating to Question 2 (n=10)

The full text screening resulted in 18 studies being retained for Question 1 and 18 studies for Question 2. There was also one study included that informed both Question 1 and Question 2.

Grey literature and other search methods

The results of grey literature searching and other search methods (e.g. citation searching) are presented on the right side of Appendix 2.

A search was conducted of grey literature using the following databases and approaches:

- Google (screened all relevant pages, generally 12-15 pages of results for each set of search terms)
- Proquest theses (screened first 100 results for each set of search terms)
- GreyLit.org (screened all results)
- Mednar (screened all results).

Search terms were based on the following terms, modified for each database “patient characteristic medico-legal complaint claim malpractice” (for Question 1), “intervention reduce medico-legal complaint claim malpractice” (for Question 2).

The results of relevant studies were: Google (n=16); Proquest theses, GreyLit.org and Mednar (n = 7).

Searching of reference lists and forward citation searching of included studies (from both peer reviewed literature and grey literature) was also conducted. There were 39 potentially relevant studies identified in the reference lists of included studies and 15 studies identified in citation searching.

As shown in Appendix 2, after assessing full texts for eligibility, there were 6 studies relevant to Question 1 and one study relevant to Question 2. Reasons for exclusion of the remaining 70 studies include:

- Duplicate record (n=5)
- Potentially relevant to Question 1 but a lower quality (ie lacking sufficient detail about patient characteristics or a control group), non-review set in the US or Western Europe (n=23)
- Potentially relevant to Question 2 but incorrect intervention type or study design and set in the US or Western Europe (n=7)
- Not relevant on full text review (n=31)
- A low quality or old literature review relating to Question 1 (n=1)
- A low quality literature review or summary of legal studies relating to Question 2 (n=3).

Evidence grading

There was a total of 44 studies included in the review: 24 studies relevant to Question 1,(20-43) 19 studies relevant to Question 2(5-9, 44-57) and one study relevant to both Question 1 and 2.(58)

The quality of the evidence was graded according to the study design using the NHMRC levels of evidence (Appendix 3).(59) These range from: level I (a systematic review of Level II studies), through to level IV (case series with either post-test or pre-test/post-test outcomes). However, due to the aetiological nature of Question 1 which could be answered using cross-sectional studies, and the low methodological quality of several included studies for Question 2, a large number of included studies were not able to be graded using the NHMRC levels of evidence. Additionally, a number of systematic reviews of non-RCTs and literature reviews were included. Therefore, an 'other' category was used to describe the study designs of those studies not fitting the NHMRC criteria. As shown in Table 2 there were six categories of 'other' study designs used.

Table 2 Summary of quality of evidence of included studies using NHMRC levels of evidence criteria and other study designs suited to aetiology and systematic reviews of non-RCTs and literature reviews.

Level	Study design	Question 1	Question 2	Total
I	A systematic review of Level II studies	0	1	1
III-2	A comparative study with concurrent controls (i.e. non-randomised experimental trials, cohort studies, case-control studies, interrupted time series studies with a control group)	4	1	5
IV	Case series with either post-test or pre-test/post-test outcomes	0	13	13
	Other (unable to be graded)	21	5	26
	Aetiological study	*0*	*1*	*1*
	Cross-sectional analysis of closed claims from national database	*8*	*0*	*8*
	Cross-sectional analysis of patient complaints from hospitals, general practice or national databases	*8*	*0*	*8*
	Retrospective mixed methods study of a convenience sample of all births in a large health service	*1*	*0*	*1*
	Survey	*2*	*1*	*3*
	Systematic review of non-RCTs or a literature review	*2*	*3*	*5*
	Total included studies	25	20	45[@]

[@] One study relevant to Question 1 and 2 was counted twice due to different study designs related to each question.

The overall quality of the evidence was poor with about two-thirds of the included studies (n=26, 65%) not aligned with study designs included in NHMRC levels of evidence. The majority of these studies (n=21) were relevant to Question 1 (Table 2). In addition, almost one-third of the studies (n=13, 33%)

were at the lowest level of evidence (level IV – Case series); all of these were relevant to Question 2. There was only one systematic review (level I evidence) that was relevant to Question 2. There were five level III-2 studies (mainly case control studies) four of which were relevant to Question 1 (Table 2).

Included studies summary

The quality and study design included studies was also appraised using an NHRMC matrix to summarise consistency, clinical impact, generalisability and applicability. The evidence base of Question 1 was rated poor (Table 3). There is a high proportion of very low and low quality studies and only four studies included a control group to compare against.

Table 3 NHMRC matrix summary for the evidence base on "Question 1: What are the common characteristics and circumstances of patients who are most likely to complain or bring a claim about the care they have received from a doctor?"

Component	A	B	C	D
	Excellent	Good	Satisfactory	Poor
Evidence base				X
Consistency			X[@]	
Clinical impact				X
Generalisability			X	
Applicability		X		

[@] Consistency based on narrative synthesis rather than meta-analysis and I^2

Consistency was rated as satisfactory only. There are a number of types of patient characteristics studied in which the evidence was either inconsistent or contradictory.

Clinical impact was rated as poor due to small effect sizes /strength of relationships between the patient characteristics and likelihood of complaining or initiating a claim.

Generalisability was rated as satisfactory due to the relatively large number of settings, specialties and patient conditions that were reported.

Applicability was rated as good given the relatively even distribution of comparable studies from the US, Canada, the UK and Australia.

The evidence base of Question 4 was rated poor (Table 4). There is a high proportion of very low and low quality studies and only one study included a control group.

Table 4 NHMRC matrix summary for the evidence base on “Question 2: What initiatives or interventions have been shown to be effective at reducing complaints about the care patients have received from a doctor?”

Component	A	B	C	D
	Excellent	Good	Satisfactory	Poor
Evidence base				X
Consistency		X[@]		
Clinical impact			X	
Generalisability			X	
Applicability			X	

[@] Consistency based on narrative synthesis rather than meta-analysis and I^2

Consistency was demonstrated across most of the intervention types, with the exception of simulation training (where only one study was included).

Clinical impact was rated as satisfactory due to the relevance of the outcomes included in most studies to the review question, and the magnitude of effect sizes, although this was adjusted downwards for the preponderance of studies without controls and/or lacking adjustment for confounders.

Generalisability was rated as satisfactory due to the relatively large number of settings, specialties and patient conditions that were reported.

Applicability is impacted by the lack of studies from comparable health systems (Australia, New Zealand, UK and Canada) and the high proportion of US studies and systematic reviews based mainly on US studies.

Findings

Question 1: What are the common characteristics and circumstances of patients who are most likely to complain or bring a claim about the care they have received from a doctor?

Characteristics of included studies

As shown previously in Table 2, 21 of 25 studies included in Question 1 are best described as 'other' study designs using NHMRC level of evidence categories, and these are mainly cross-sectional studies of complaints/claims that simply report the underlying characteristics of a claims database, and do not relate it to underlying patient populations or control groups. The lack of information from the entire patient population or a control group precludes calculation of whether a patient characteristic is under- or over-represented in the claims/complaints database. The focus of these papers is more often to report trends in litigation rates or amounts over time, or to discuss common causes of litigation or technical and non-technical contributing factors. The reporting of patient characteristics in many of these studies is relatively cursory and is incidental to the main purpose of the study. Therefore, the vast bulk of the evidence base provided by such studies is relatively uninformative apart from providing purely descriptive statistics about patients who complain or make claims.

Only four studies included a comparative group which allowed comparison of rates, or likelihood, of claims/complaints in a particular patient demographic group compared to a different group. Two of these studies were conducted in the UK and two were conducted in the US. For example, one study compared case notes from 42 patients who died in hospital and whose next of kin submitted a letter of complaint, with 72 controls matched for age, sex, ward location and time of death. This study was able to determine that treatment escalation limitation plans were used less frequently in cases than controls, and quality of care was lower in cases than controls, suggesting a relationship between these variables and whether a complaint is made.

There was a total of 40 types of patient characteristics described in the 25 studies. For the purpose of Question 1, we included relevant patient characteristics that were statistically significant in a comparative case-controlled study or where the patient characteristics was discussed in more than one of the examined studies. Consequently, fourteen of these characteristics were included in more than one study and one additional patient characteristic was included due to its being statistically significant. These are listed in Table 5. Findings for each of these patient characteristics are presented separately below.

The characteristics of studies included for Question 1 are reported in Appendix 4. The most common countries of setting were UK (7 studies, 28%) followed by Canada (5 studies, 20%), Australia and the

US (3 studies each, 12% each), Ireland (2 studies, 8%), Germany, Sweden and Denmark (1 study each, 4% each). There were two systematic reviews with no study setting.

Table 5 Summary of types of patient characteristics included in Question 1 studies (included in more than one study)

	Study design					
Patient characteristic[a]	Comparative (n=4)	Cross-sectional (n=16)	Retrospective mixed methods study (n=1)	Survey (n=2)	Systematic review of non-RCTs or literature review (n=2)	Total
Age	4	13	1	1	0	19
Sex	4	11	0	1	1	17
Patient risk factors	2	6	1	0	0	9
Therapeutic context	1	5	0	0	0	6
Complainant	1	4	0	0	1	6
Race	2	2	0	1	0	5
Employment status	1	1	0	2	0	4
Length of stay	2	1	0	0	0	3
Complication	2	1	0	0	0	3
Insurance status	1	1	0	1	0	3
Marital status	0	0	0	2	0	2
Education	0	0	0	2	0	2
Relationship with the clinician	0	1	0	0	1	2
Mental, behavioural and neurodevelopmental disorders[b]	1	0	0	0	0	1

[a]Characteristics must have been reported in more than one study to be included in this table. Each study may report on more than one characteristic.

[b]Only included in one study, but included due to being statistically significant

American Society of Anaesthesiologists classification

Nearly two-thirds of studies (16, 64%) were set in in-patient hospital settings and seven (28%) were mixed across primary care, in-patient and specialist care. Two studies (8%) were set in primary care. Surgical specialists (e.g. neurosurgical, abdominopelvic, laparoscopic, general and breast surgery), were the most reported (n=7 studies, 28%). This was followed by studies looking at mixed specialisations (e.g. general cross-sectional analyses of a database, or medical and surgical wards; n=3 studies, 12%) as well as maternity and neonatal specialties (n=2 studies each, 8% each).

Twelve studies (48%) addressed complaints, seven studies (28%) addressed malpractice litigation, one study (4%) addressed regulatory complaints and five (20%) addressed a combination of complaints, malpractice litigation and regulatory complaints. Four studies specified whether the claim was warranted or unwarranted with two studies noting the claim to be warranted,(30, 40) one study noting the claim to be unwarranted,(20) and one study noting the claim to be both warranted and unwarranted.(27) The remaining studies did not address this issue.

Age

Age is the most common patient characteristics examined in the studies analysed for Question 1. These studies were generally cross-sectional analyses of patient complaints and claims from various health related institutions, such as internal hospital records (n=3) and national databases (n=9). In addition, there were four comparative studies with concurrent controls in the in-patient hospital (n=3) and mixed settings (n=1), as well as a retrospective mixed method study (n=1) and a survey (n=1) both in an in-patient hospital setting. Generally, these studies reported age as a range (n=3), mean (n=6) or median (n= 6) and percentage in age groups (n=7). A summary of these studies is set out in Table 6.

Table 6 Summary of reported age statistics (years) for complainants/claimants in included studies sorted by study design

Study	Age Range	Mean Age	Median Age	Population
Comparative study with concurrent controls (n=4 studies)				
Robin Taylor et al. 2020(41)	56 to 92	75.4	-	-
Kynes et al. 2013(33)	0.7 to 15 (paediatric) 28 to 73 (adult)	6 (paediatric) 52.5 (adult)	-	-
Jones et al. 2021(31)	72 to 87	-	81 (compliments) 79 (study cohort)	-
Grandizio et al. 2021(28)	-	53 (complaints)	-	-

Study	Age Range	Mean Age	Median Age	Population
		49 (control group)		
Cross-sectional analysis of patient complaints (n=13 studies)				
Bujoreanu et al. 2020(21)	3 to 98	48.3	-	11.9% under 18 years 36,7% between 19–40 years 25.2% between 41–60 years 26% over 61 years
Calder et al. 2019(22)	-	-	-	13.2% under 18 years 71.7% between 19–64 years 15.1% over 65 years
Calder et al. 2022(23)	-	-	-	6% under 18 years 8% between 19–29 years 42% between 30–49 years 28% between 50–64 years 16% over 65 years of age
Coysh and Breen 2014(24)	-	-	-	Unknown (Although modal age between 36–45 years)
Crosbie et al. 2022(25)	-	-	-	8.3% under 18 years 10.3% between 19–29 years 31% between 30–49 years 18.6% between 50–64 years 15.2% between 65–79 years 5.5% over 80 years 11% age unknown
Elias et al. 2021(26)	21 to 95	62.7	67.5	-
Kynes et al. 2013(33)	-	-	43	-
Lefebvre et al. 2021(34)	-	-	47	-
McSweeney et al. 2021(35)	-	52	54	14.6% under 30 years 24.7% between 30–49 years 26.5% between 50–69 years 25.6% over 70 years 8.7% age unknown
O'Connell et al. 2021(37)	-	46	-	-
Rennie et al. 2019(40)	-	Unknown	-	-
Schnitzer et al. 2012(42)	-	Unknown	-	7.4% under 18 years 46.8% between 19–64 years 37.7% between 65–79 years 8.1% over 80 years

Study	Age Range	Mean Age	Median Age	Population
Vilos et al. 2017(43)	14 to 65	-	31	-
Survey (n=1 study)				
Kearney et al. 2020(32)	-	-	-	Percentage likely to sue in each age group: 30% between 18–24 years 38% between 25–34 years 35% between 35 –44 years 34% between 45–54 years 32% between 55–64 years 50% over 65 years
Retrospective mixed methods study (n=1 study)				
Nowotny et al. 2018(36)	-	-	-	-

The results of particular relevance are the four comparative studies with concurrent controls.(28, 31, 33, 41) Overall, the results suggest that higher patient age within a given patient population may be weakly correlated with greater likelihood of complaint. For example, Kynes et al. described the distribution of complaints among anaesthesia providers and identified factors associated with complaint risk in paediatric and adult populations.(33) This US study analysed a complaint database for an academic medical centre. Complaints were recorded as comments during postoperative telephone calls from July 2006 to June 2010 from ambulatory surgery patients regarding the quality of their anaesthesiology care. Risk factors were grouped into patient demographics (including age), procedural, and provider characteristics. The study found that patient complaints about the provision of anaesthesia care were not evenly distributed among anaesthesiologists, and certain patient and procedural factors contributed to increased complaint risk. In the specified subgroups in an ambulatory surgery setting, paediatric patients, older patient age and case delay were each associated with increased complaint risk whereas general anaesthesia was associated with decreased risk.

The study by Jones et al. in the UK explored the frequency and nature of complaints and compliments reported to Patient Advice and Liaison by individuals undergoing surgery for a chronic subdural haematoma.(31) Patients who complained about their care were slightly older (median age 79, interquartile range 72-85) compared to all patients (median age 77, interquartile range 69-84).(31) However, in this study patients who complimented the service on their care were also slightly older (median age 81, interquartile range 68-87) compared to all patients (median age 77, interquartile range 69-84).(31)

Robin et. al's study assessed quality of care among patients who died in hospital and whose next-of-kin submitted a letter of complaint.(41) This UK study made comparisons with matched controls to identify whether use of a treatment escalation and limitation plan affected the principal outcomes. The index cases were consecutive patients who died in the three district general hospitals analysed by the

study between January 2015 and December 2017, and whose next-of-kin submitted a letter of complaint after their death. For each index case, two controls were selected. These were patients who had also died in hospital, matched for age (to within 10 years), sex, hospital ward and time of death (within one month of cases) but for whom there was no complaint. Unsurprisingly given the matching on age, there were no significant differences in age between cases (mean 75.5 year, range 56-92) and controls (mean 77.0, range 51-95).(41)

Finally, Grandizio et al. aimed at defining and categorising patient complaints within a US hand surgery practice over a 10-year period as well as defining surgeon and patient factors associated with formal complaints.(28) The study examined all patients who filed a complaint with the institution's patient advocacy service against six hand surgeons in an academic practice over a 10-year period. Complaints were recorded and categorised using the Patient Complaint Analysis System. A control group consisting of all patients seen by the surgeons during the study period was created. Demographic differences between the complaint and control groups were analysed, as were complaint rates between surgeons. For each patient who filed a complaint, baseline demographics, including age, was recorded. The study found that during the period, 73 of 36,010 unique patients seen (0.20%) filed a complaint. Being consistent with other case-controlled studies, the mean age of patients who made a complaint (53 years) was slightly higher but not statistically significantly compared with the control group (49 years).

In all the studies summarised in Table 6, patient age differed significantly depending on the patient population studied. No conclusion could be reached on an age at which complainant risk increases as it is dependent on other variables such as procedure, geography, and patient population. Although a number of studies suggested that a higher age within a given patient population tended to equate with increased risk of complaint, age was not identified as a significant predictor of patient complaints or claims in any study.

Sex

Seventeen studies examined sex as a relevant patient characteristic when assessing likelihood of initiating complaints or claims against a doctor. Like the findings in patient age, studies examining patient sex were also predominantly cross-sectional analyses of patient complaints and claims from hospital records (n=4) and national databases (n=7). In addition, there were four comparative studies with concurrent controls in the in-patient hospital (n=3) and mixed settings (n=1), as well as a systematic review of non-randomised control trials (n=1) and a survey (n=1) both in in-patient hospital settings.

The same four comparative studies with concurrent controls that examined patient age also examined patient sex.(28, 31, 33, 41) The reviewed studies generally provided a consensus that female patients or female relatives of male patients were more likely to make complaints than male patients.

Kynes et al. found that in adult patients, speaking to the patient, female gender, and not using general anaesthesia each showed some evidence of increased risk associated with a complaint, although the author cautioned against the overinterpretation of these unadjusted comparisons that were subject to confounding.(33) The study did conclude that male gender and general anaesthesia were associated with decreased risk of complaints in adults. For the paediatric patient population, the study was unable to ascertain and explore the gender of the survey respondent and its impact on patient complaints. Similarly, both Jones et al. and Grandizio et al. found that the female gender showed a

higher propensity for making complaints.(28, 31) In Jones et al. within the overall studied patient population 16% were females compared with 26% of the complainant population and 0% of the compliment population.(31) Likewise in Grandizio et al. female patients made up 55% of the patient population compared with 62% of the complainant population. However, in both studies, the results were not statistically significant.(28)

Unsurprisingly given the matching on sex, there were no differences in gender between cases (62% male) and controls (61% male) in Robin Taylor et al.'s study, however, the complaints were actually made by next of kin, whose gender was not reported.(41)

The results of the other included studies are generally consistent with the case control study findings. In all the reviewed studies, the included population generally had more female patients than male patients due to differences in the consumption of healthcare by the sexes. In addition, more complaints were initiated by female patients than male patients.(26, 28, 35, 37) In addition, Bujoreanu et al. and Eriksson et al. found that where complaints were filed by relatives of the patients, complainants were predominantly a female relative of a male patient, suggesting that the sex aspect of complaining is more complex than often conceptualised.(21, 27)

Patient risk factors

Nine studies of patient risk factors examined pre-existing patient risk factors, or patient indicators, potentially linked to making complaints or claims against doctors. Two studies had control groups(28, 31), seven were uncontrolled. (23, 30, 34, 36, 40, 42, 43) The types of risk factors include obesity as measured by body mass index (BMI), American Society of Anaesthesiologists (ASA) classification, previous surgery and re-operation rates, chronic diseases, and risks specific to patent groups such as neonates and pregnant women.

Obesity, American Society of Anaesthesiologists (ASA) and Body Mass Index (BMI) Scores

Three studies used American Society of Anaesthesiologists classification (i.e. ASA scores) as a measure of complainant patient characteristics. The reviewed studies examined complainant characteristics using a variety of study designs. In studies examining patient ASA and BMI, study designs included two cross-sectional analyses of patient complaints and claims from national databases (n=2) as well as one comparative study with concurrent controls in an in-patient setting (n=1).

ASA scores are used as a measure of preoperative physical status. The ASA score is a subjective assessment of a patient's overall health that is based on five classes (I to V).

- "I" means the patient is a "normal healthy patient".
- "II" means the patient has "mild systemic disease".
- "III" means the patient has "severe systemic disease" that is not incapacitating.
- "IV" means the patient has "severe systemic disease that is a constant threat to life".
- "V" means a moribund patient who is not expected to live more than 24 hours without surgery.

Jones et al. was the only case-controlled study examining ASA scores as a measure of patient characteristics and its effect on patient complaints.(31) While the results showed that patients with ASA scores greater than or equal to III were less likely to make a complaint and more likely to provide a compliment, the result was not statistically significant.

Grandizio et al.'s study was the only case-controlled study that examined BMI as a relevant patient indicator.(28) The results showed that in patients with BMI above 30, a lower proportion (41%) made a complaint compared with the patient population of 46%. Similarly in Jones et al. the results were not statistically significant.(31)

The other uncontrolled studies that examined ASA score or BMI did not provide a valuable indicator on the effectiveness of ASA score or BMI as a patient complainant characteristic. In summary, there is very little evidence supporting a relationship between either ASA score or BMI and rate of complaints.

Other patient risk factors

Calder et al. and Hawdon et al. used cross-sectional analysis of patient complaints data from national databases,(23, 30) whereas Nowotny et al. utilised a retrospective mixed method approach and survey in the in-patient hospital setting.(36) On the other hand, both Rennie et al. and Calder et al. examined patient indicators as part of patient characteristic assessment.(23, 40) All studies used an uncontrolled cross-sectional design.

Calder et al. examined trends and contributing factors in medico-legal cases involving spinal surgery.(23) While the author acknowledged a lack of information about patient risk factors, the study did examine two risk factors – patient obesity and whether the patient had any previous spinal surgery – as part of the patient characteristic assessment. In addition, examined patient indicators as a factor in medico-legal cases involving spinal surgery.(23) In that regard, Calder et al. also reported that peer experts identified intraoperative injuries (32.6%), diagnostic errors (15.7%), and wrong site surgeries (18.0%) as the top patient safety indicators. Jones et al. recorded re-operation rates and found that 6/15 (40%) of patients who complained had experienced a re-operation, however re-operation rates from the whole population were absent.(31)

Hawdon et al. examined complaints relating to instances of neonatal hypoglycaemia.(30) The discussion around risk factors related to early diagnosis and treatment in babies at risk of neonatal hypoglycaemia. Rennie et al. did not address the issue of patient indicators directly but discussed it in the context of diagnosis and treatment for babies at risk of hyperbilirubinemia and kernicterus.(40)

Owing to the different study design used by Nowotny et al. risk factor assessment was identified from surveys completed by clinicians.(36) This study assessed patient likelihood of complaining and making claims against the physician from maternity care by assessing the physician's awareness of potential patient risk factors. The findings showed that physicians were generally better at recognising risk factors for legal claims than for patient complaints.

Therapeutic context

The concept 'therapeutic context' is used here to describe aspects of treatment, diagnosis, setting and/or phase of care that may be related to likelihood of a complaint or claim. There were six studies that addressed at least one aspect of the therapeutic context, all but one (28) were uncontrolled cross-sectional studies with limited ability to assess the effectiveness of treatment as a patient characteristics to inform the likelihood of patient complaints. (22, 24, 34, 42, 58)

Grandizio et al. was the only case-controlled study examining patient treatment.(28) In that study it was noted that the highest percentage of patient complaints were categorised within the care and

treatment domain (30%). Of the 33 complaint designations in this domain, diagnosis or treatment discordance associated with nonsurgical care was the most frequent, followed by dissatisfaction with surgical care. Although eight patients with a complaint had a surgical complication and required revision surgery, only six of the patient complaints were actually related to the surgical complication with the other two complaints related to the access and availability domain.

Lefebvre et al.'s discussion on treatment revolved around the appropriate risk-based management approach to injury by the physician.(34) These approaches included statistics on intraoperative repair, returning a patient to the operating room, transfer to a tertiary care centre, transfer to an intensive care unit or providing conservative treatment. The treatment given was then measured against patient outcome (including harm). Barragry et al. focused on physician complaints in general practice during the out of hours setting.(58) The results showed that the largest proportion of complaints related to either a delay or a failure in diagnosis or referral that occurred, usually when the condition worsened, and required further medical attention. Coysh and Breen showed that for US neurology and neurosurgery claims, 63.1% of claims were due to negligence in neurosurgical care, whilst 36.9% were due to negligence in neurological care.

The setting was compared in Calder et al.'s examination of surgical fires and burns in hospital operating rooms and clinic operating rooms.(22) The results showed a significantly higher instance of surgical burns in the hospital operating environment (81.1%) as compared with clinic operating settings (18.9%), however there were no calculations of rate of burns adjusted for number of patients treated in the different settings. Similarly, Schnitzer et al. examined complaints from three German regions.(42) While they reported the majority of complaints were from Western Germany (70%), with the remainder from Eastern Germany (19.9%) and Berlin (9.9%), there was no adjustment for population or patient volume from these three regions.

Complainant

The third most common patient characteristic examined was the identity of the complainant (i.e. were they a patient or their relative or carer). The reviewed studies examined complainant characteristics using a variety of study designs including cross-sectional analysis of patient complaints and claims from general practice (n=1) and hospital records (n=3). In addition, there was also one comparative study with concurrent controls in the in-patient hospital setting (n=1) as well as a systematic review of non-randomised control trials (n=1).

The only case-controlled study examining complainant as a patient characteristic is by Jones et al.(31) This study showed that non-patients were more likely to initiate complaints compared with patients. Only 20% of complaints were made by patients while 80% were made by non-patients. Conversely, 90% of compliments were made by patients and only 10% were made by non-patients.

The results in Jones et al. are supported by the majority of the other non-case-controlled studies.(31) For instance, both Elias et al. and Eriksson et al. found that non-patients had a higher inclination to make complaints compared with patients, however the results were not statistically significant.(26, 27)

Barragry et al. undertook an observational study of a GP co-operative practice in Ireland.(58) Among other things, the study examined complainant demographics including the source of complaint (whether it was the patient themselves, their relative or others). In 90% of complaints, there were no adverse medical outcomes. The study found that most complaints (59%) were not made by the

patient themselves, but by a family member on their behalf. The largest category of complainant were mothers of minors (35%). Analysis showed that those most likely to make a formal complaint were female (70%), private patients (73%) and the complaint related to the care of minors (45%) aged 18 or younger, who comprised 41% of all patients attending during the study period.

Two exceptions to the general trend of predominance of non-patient complainants are noted. The first is the systematic review by Reader et al.(39) which found that in the 36 analysed studies (comprising 44 211 complaints) reporting on the complainant, 64% were patients and 26% were family; data was not provided about who reported the remaining 10% of complaints. In the 33 studies (comprising 36 612 complaints) reporting the target of the complaint, 86% were medical staff, 6% were nursing staff and 8% were other.

The other exception is an examination of complaints received by the ear, nose and throat (ENT) department of two large teaching hospitals in London in order to determine current trends in patient complaints and claims.(21) This study found that the majority of complaints were filed by patients themselves, followed by their relatives. These complaints were most commonly directed at the administrative team (52%), with management (23.5%), the physician (16.9%), the nursing staff (5.3%), and allied healthcare professionals (2%), respectively, being the target group for the rest of the complaints. Furthermore, 61.4% of patients complained about more than one aspect of their care.

In summary, there is mixed evidence about whether non-patients or patients are more likely to complain about healthcare. While a number of studies have demonstrated non-patients are more likely to complain than patients, a 2014 systematic review of 36 studies concluded otherwise, reporting that patients accounted for 64% of complaints and family members accounted for only 26%.

Race

Five studies examined race as a relevant patient characteristic in the initiation of a patient complaint or claim against their doctor. Elias et al. and Rennie et al. used cross sectional analysis of closed claims from hospital and a national database respectively.(26, 40) Grandizio et al. and Kynes et al. both undertook a comparative study with concurrent controls.(28, 33) Finally, Birkeland et al. used a survey method to examine complaints relating to prostate cancer in the primary care setting.(20)

The results show that race is not a determining factor in patient characteristics relevant to Question 1. In the case-controlled studies, both Caucasian and non-Caucasian patients had a similar risk of making a complaint. Grandizio et al. examined race as part of the study's baseline patient demographic assessment.(28) While the data showed a lower incidence of white patients in the complainant group (93%) compared with the control group (96%), this reduction was not statistically significant. Similarly in Kynes et al. race was assessed in both the paediatric and adult patient populations with Caucasian and non-Caucasian patients showing a comparable risk of complaining.(33) As per Grandizio et al. this was not statistically significant.(28)

In the non-case-controlled studies it could not be determined if race was a useful indicator for predicting complainant risk.

Employment Status

Four studies examined employment status as part of complainant patient characteristics. The reviewed studies examined complainant characteristics using a variety of study designs including two patient surveys in Denmark and Ireland (n=2), one comparative study with concurrent controls in a mixed setting (n=1) as well as a cross-sectional analysis of patient complaints from a national database (n=1).

The main comparative study here is Grandizio et al.(28) In the study, the patient's employment status was discussed and recorded as part of capturing baseline demographic data. The results showed a lower level of employment in complainants compared to the control group (36% of complainants were employed compared to 41% in the control group).

In other non-controlled studies, Kearney et al. also captured employment status and income as part of the patient questionnaire.(32) The results reaffirm Grandizio et al.'s study in that unemployed patients were more likely to sue compared to patients who were employed.(28) In addition, patients who were retired and students also had a higher tendency to sue compared to patients with ongoing employment.

On the other hand, in their 2012 study, Schnitzer et al. found that unemployed patients and patients on welfare in Germany had a lower likelihood of complaining (8.9%) as compared to employed patients (20.6%).(42) Surprisingly, retirees excluding pensioners had a significantly higher likelihood of complaining than was posited in Kearney et al. at 53%.(32) Furthermore, in Schnitzer et al. the study also goes further to examine the instances of complaints relating to unjust policies, refusal/restriction of drugs, refusal/restriction of non-drug treatments and physician-patient relationships when measured against the patient's employment status.(42) The study noted that complaints about unjust policies were also voiced more frequently by people with serious financial problems. A large proportion of complainants who were unemployed or receiving welfare benefits (35.0%) criticised the injustice of health policy unrelated to the institution due to increased financial obligations for obtaining treatment.(42)

In summary, there was mixed evidence in assessing the relationship between employment status and rate of complaints.

Length of hospital stay

Three studies examined a patient's length of hospital stay. Robin Taylor et al. and Jones et al. were both comparative studies with concurrent controls in the in-patient hospital setting.(31, 41) Rennie et al. used a cross-sectional analysis of closed claims from a national database in a mixed setting.(40)

The two case-controlled studies showed that shorter stays were generally associated with higher likelihood of complaint. In Jones, Davies *et al*. it was found that while overall not statistically significant, there was a trend for complaints to become more likely with length of stay up to 15 days.(31) Similarly, Robin Taylor, Bouttell *et al*. found that the complainant population had a lower average length of stay days (11.8 days) compared with the overall patient population (15.5 days).(41)

In Rennie, Beer *et al*. length of stay was only discussed in the context of diagnosis and readmission times for babies at risk of hyperbilirubinemia and kernicterus and was thus not relevant to the assessment of length of stay as informing patient complainant characteristics.(40)

Complications

Three studies assessed patient complications as characteristics relating to patient complaints and claims against their doctor. In studies examining patient complications, study designs included two comparative studies with concurrent controls (n=2) and one uncontrolled cross-sectional study (n=1).

Grandizio et al. and Jones et al. (19, 22) are the two case-controlled studies examining patient complications. In Grandizio et al., a manual chart review was conducted for each complaint using the electronic medical record system to determine the diagnosis, type of treatment and any complications resulting from surgery. Both minor and major complications (including re-operations) were recorded. Although eight patients with a complaint had a surgical complication and required revision surgery, only six of the patient complaints were actually related to the surgical complication. The remaining two patients with surgical complications had complaints regarding access and availability.

Similarly Jones et al. recorded in-hospital complications as part of the patient characteristics.(31) The in-hospital complications included myocardial injury (troponin above 14 ng/L) or acute kidney injury (>50% rise in creatinine above baseline).

Patient complaints in the context of diagnosis and treatment of hyperbilirubinaemia and kernicterus were discussed in the uncontrolled cross-sectional study.(40) However, like other uncontrolled studies, the study's value in assessing patient complainant characteristics is limited.

Insurance status

Three studies examined the patient's insurance status as a measure of patient characteristics relating to complaints and claims against doctors. Study designs include the use of a patient survey (n=1), cross-sectional analysis of patient complaints from a national database in a mixed setting (n=1) as well as a comparative study with concurrent controls also in a mixed setting environment (n=1).

Grandizio et al. measured not only whether the patient had insurance or not but also the insurance type (e.g. private insurance, Medicaid, Medicare, self-pay, worker's compensation or other).(28) The study found that holders of private insurance or Medicare were more likely to initiate complaints than the control group whereas for all other insurance categories, it was the reverse. Similarly, Kearney et al. reported that holders of medical cards were most likely to sue (55%), followed by others (50%), private health insurance holders (47%) and finally self-funded patients (43%).(32) The study concluded that those patients who were currently unemployed or retired, without dependents, divorced and with public health insurance were more likely to sue. Similarly, a multivariate analysis by Schnitzer et al. showed that complaints about the topics under examination were more likely to be lodged by people with statutory health insurance, people in a precarious financial situation, people with chronic disease or those with multimorbidity and women.(42)

Marital status

Birkeland et al. and Kearney et al. examined marital status as part of their patient characteristic assessment.(20, 32) Both studies employed a survey study design.

In Birkeland et al. marital status was assessed in categories of couples who live together, couples living apart and singles.(20) The results showed that couples living together were less likely to

complain as compared with couples living apart and singles. Kearney et al. used marital status as a measure of the patient's socioeconomic position.(32) The results generally mirrored Birkeland et al. where singles and divorcees were found to have a higher likelihood to sue (at 35% and 55% respectively) compared with married couples (33%) and separated couples (27%).(20)

Education

Two studies examined patient education as part of patient characteristic mapping. Both Kearney et al. and Birkeland et al. used a survey in an in-patient hospital setting in Ireland and Denmark respectively.(20, 32)

In Kearney et al. assessment of patient education was used as part of a broader assessment of the patient's socioeconomic position.(32) The data showed that higher educational attainment resulted in a higher likelihood to sue. On the other hand, Birkeland et al. found that lower education was associated with an increased wish to complain.(20) In particular, men with lower education expressed an increased wish to complain with a clear gradient across the level of education achieved.

Patient clinician relationship

Two studies examined the patient's relationship with the doctor. Harrison et al. used a cross-sectional analysis of patient complaints from a national database in Australia,(29) whereas Oyebode used a systematic review of non-randomised controlled trials in an in-patient hospital setting.(38)

In Harrison et al. only 28 (13%) of the 138 complaints were associated with patient-clinician relationship factors. The assessment of relationship was broken down into communication (n=24) (including communication breakdown; incorrect information; patient-physician dialogue); humaneness/caring (n=4) (including respect, dignity and care); as well as patient rights relating to consent (n=4).(29). Oyebode on the other hand examined the relationship between clinical errors and malpractice claims.(38) While the author recognised the relationship was complex, the study concluded that probably no more than one in seven adverse events in medicine result in a malpractice claim and the factors that predict a patient will resort to litigation include a prior poor relationship with the clinician and the patient feeling that they are not being kept informed.

Mental, behavioural and neurodevelopmental disorders

We also included Grandizio *et al*.'s assessment of mental, behavioural and neurodevelopmental disorders as a patient characteristic in patient complainant behaviour. (28) This was the only study included in the Evidence Check to examine mental, behavioural and neurodevelopmental disorders, defined as any International Classification of Diseases (10th revision) code from F01 to F99 contained within the patient's electronic medical records.

The results indicated that underlying mental health conditions are associated with higher rates of patient complaints. Patients with a complaint had a significantly higher percentage of mental, behavioural, or neurodevelopmental disorders compared with the control (55% compared with 42% respectively, p=0.03). No further details were provided about which types of disorders were more prevalent in either the complaints or control datasets.

Gaps in the evidence

For Review Question 1, there were only four case-controlled studies allowing comparative evaluation between the assessment group with a control. The many uncontrolled and unadjusted cross-sectional studies of complaints/claims that simply report the underlying characteristics of a claims database do not provide particularly useful insights into the relationship between patient characteristics and rates of complaints or claims.

Enhanced collection of patient characteristic data by regulation agencies, healthcare complaints entities and medical indemnity insurers may facilitate improved quality of research to inform risk management policy and practice.

Question 2: What initiatives or interventions have been shown to be effective at reducing complaints about the care patients have received from a doctor?

Characteristics of included studies

As shown previously in Table 2, 18 of 20 (90%) studies included in Question 2 are best described as either NHMRC level IV evidence, or 'Other' study designs. These study designs are at clear risk of bias and therefore the strength of findings from such studies will be considered 'poor'.

There were seven types of interventions included in the 20 studies that assessed effectiveness of interventions to reduce complaints (Table 7). Findings for each intervention type are presented separately below. Interventions such as caps on compensation and attorney fees, and alternative payment system and liabilities(46) were excluded from the review as they are not doctor-directed interventions. Impacts of these medical malpractice reforms have been recently summarised.(60, 61)

Table 7 Summary of types of interventions included in Question 2 studies

Intervention design	Systematic review	Comparative study with concurrent controls	Case series	Other	Total
Risk management program	0	0	5	1	6
Communication and resolution program	0	0	3	1	4
Peer program	0	0	2	1	3
CPD participation	0	1	0	1	2

Intervention design	Systematic review	Comparative study with concurrent controls	Case series	Other	Total
Medical remediation program	0	0	2	0	2
Shared decision-making	1	0	0	1	2
Simulation training	0	0	1	0	1

CPD = Continuing Professional Development

The characteristics of studies included in Question 2 are summarised in Appendix 4. The most common country of setting was US (10 studies, 50%) followed by Canada (3 studies, 15%), the UK, New Zealand, Denmark and Ireland (1 study each, 5% each) and there were three literature reviews (no study setting). Nearly half of the studies (9, 45%) were set in in-patient hospital settings and 8 (40%) were mixed across primary care, in-patient and specialist care. Two studies (10%) were set in primary care. A mix of specialties was most commonly reported (11 studies, 55%). Nine studies (45%) addressed malpractice litigation, 6 (30%) addressed complaints, and one (5%) addressed both, regulatory notifications and three were not applicable. Only one study specified whether or not the complaint/claim was warranted (this study focussed on warranted complaints).(9)

Risk management programs

Six studies assessed the effectiveness of risk management programs or risk reduction strategies on claims and complaints, including studies in which the intervention was primarily educational in nature (but distinct from Continuing Professional Development [CPD]). These were all uncontrolled before and after studies based in general practice (n=1) and hospital settings (n=5); obstetrics featured in three of the hospital studies. The risk management programs were heterogeneous in nature, and were described in terms such as: “a formal approach encompassing evaluation of complaints, improved communication in relation to complaints, and more direct use of insights gained from complaints analysis” by Barragry et al. (58), “an introductory lecture followed by a mock lawsuit” by Juo et al. (49), “three educational modules, each about 12 months in length” by Milne et al. (51) and analysis of closed medical negligence claims by physician groups by Pegalise et al.(54)

Overall, results demonstrated a consistent effect of reduced rates of claims and complaints following implementation of risk management programs. Reduced costs from malpractice claims, more timely responses and improved staff satisfaction, knowledge, confidence, perceptions of culture and preparedness for a claim were all reported. However, the study designs (uncontrolled before and after) were uniformly weak and there was little, if any, adjustments for other secular trends in claims or confounders, and no control sites. Additionally, there was rarely any evidence provided about the extent of implementation or sustainability of the intervention, many of the studies had low sample sizes and most studies were limited to a single hospital/health service.

Barragry et al. introduced a co-operative risk reduction strategy for Irish general practitioners including procedural change, focused training and education.(58) The intervention was based on an analysis of complaints (Table 8). Following introduction of the risk reduction strategy, the complaints rate reduced by 36%, from 0.77 to 0.49 per 1000 consultations (p = 0.02) between the two periods of data collection. Timeliness of response from the general practice co-operative to the complainant improved from 63% to 75%. Notification of complaint to the patient's GP improved from 48% to 96%.

Table 8. Components of a co-operative risk reduction intervention for Irish GPs (Table 3 from Barragry et al.(58))

Study design
Specialist general practice training became a condition of co operative membership
All late "red eye" shift doctors required to attend quarterly CME meetings on selected topics/problem case reviews
Regular patient satisfaction surveys conducted, and reflected back to co-operative members in detail
Increased frequency of emergency skills training (BLS/AED)
Risk management seminars conducted on site for members
Improved induction training and support of GP registrars
GP registrar appointed to co-operative medical committee
Individual doctors, where felt appropriate by Medical Committee requested and required to attend Regional CME tutor for CME

AED – Accident and Emergency Department, CME – Continuing Medical Education, BLS – Basic Life Support, GP - General Practitioner.

Diraviam et al. described implementation of a risk reduction strategy at University of Pennsylvania Health System.(5) The strategy included an analysis of complaints and implementation of the Patient Advocacy Reporting System (PARS®) that also entailed peer review and a Professionalism Committee to manage professionalism issues beyond patient complaints. A bottom-up approach was also used to actively engage physicians in risk mitigation and malpractice reduction within their respective departments in the Risk Reduction Initiative. There were three case reports presented: difficult airway rapid response, strengthened culture of safety in obstetrics and Gynaecology, and disclosure of medical error. The primary measure of the success of the initiative was the reduction in malpractice costs from approximately 4% of total patient service revenues in 2009 to 2% in 2016. The average annual volume of claims was reduced by approximately 33% during the same seven-year period (2009–2016).

As described by Milne et al. the MORE^{OB} Program in Canada consists of three educational modules, each about 12 months in length: 'Learning together', 'Working together' and 'Changing culture'.(51)

The modules teach core obstetric content to ensure all members of an obstetric unit (e.g. nurses, midwives, family physicians, and obstetricians) have a similar foundation of clinical knowledge. The average knowledge score increased post-test for all professions compared to pre-test scores. Additionally, inter-professional variation in knowledge decreased. Improvements in the Culture Assessment Survey ranged from 5-20% from pre- to post-test scores. A significant reduction ($P < 0.001$) was shown in average incurred costs in the obstetrics labour and delivery units after the onset of the program. The number of catastrophic infant claims decreased to 0-2 per year post intervention from a pre-intervention baseline of 3-4 per year.

Pegalis et al. identified two physician groups that have actively implemented findings from closed claims reviews: anaesthesia and obstetric physician societies in the US.(54) The groups developed and implemented safety guidelines and mandatory standards that resulted in reductions in deaths, for example from 1-2 per 10,000 anaesthetic procedures to 1 per 200,000 procedures, and reduced premiums and improved staff satisfaction. In obstetrics, a completely redesigned patient safety process led to improved perinatal outcomes and lower maternity and fetal injury rate, lower primary caesarean delivery rate, and reduced rates of litigation.

Juo et al.'s intervention comprised a two hour educational intervention consisting of an introductory lecture followed by a mock lawsuit, which was collaboratively organised by surgical staff, hospital risk management and malpractice attorneys.(49) Two medical malpractice attorneys acted as defence and plaintiff attorneys while an attending surgeon experienced in litigation acted as defendant. The study was set at one Californian hospital and involved 40 residents and attending surgeons. There were significant improvements in all measured competencies after the mock lawsuit, including confidence and mental preparedness. In comparison with attending faculty, residents obtained greater improvements in understanding the essential elements of a medical claim (1.9 vs 1.1, $p = 0.03$), gaining confidence doing a deposition for medical litigation (1.9 vs 0.9, $p < 0.01$) and understanding the do's and don'ts when named in a lawsuit (2.0 vs 1.1, $p = 0.01$).

Raper et al. conducted an uncontrolled before and after study in surgery at the Clinical Practices of the University of Pennsylvania (CPUP).(55) A series of risk reduction initiatives were carried out to raise staff awareness about strategies for defence against malpractice claims. Claims from surgery were significantly less than from the whole hospital (74.07% vs 81.07%; $p < 0.05$) (expressed as a percentage of the 5-year mean value preceding implementation of the initiative program). The mean yearly indemnity paid by the Department of Surgery was significantly less than that of the other hospital departments (84.08% vs 122.14%; $p < 0.05$). Department of Surgery-paid expenses were also significantly less (83.17% vs 104.96%; $p < 0.05$), and surgical malpractice premiums declined from baseline, but remained significantly higher than CPUP premiums.

Communication and resolution programs (CRPs)

Four studies assessed the effectiveness of 'communication and resolution programs' (CRPs) in reducing complaints and claims. CRPs aim to better communicate adverse events to patients, investigate and explain what happened; provide emotional support; and apologise and proactively offer compensation if appropriate.(50) CRPs involve communication between doctor and patient outside the court setting to reach a mutual agreement to resolve the dispute and fair compensation and include apology laws in which apologies made by medical practitioners cannot be used as evidence in medical malpractice litigation.(46) Overall, results were consistent across the four studies

in showing lower rates of claims and complaints, lower claim amounts, and faster resolution of claims following implementation of CRPs. One study demonstrated improved patient satisfaction. However, the study design (uncontrolled, before- and- after) is uniformly weak and there is little, if any, adjustments for other secular trends in claims or confounders, and no control sites. Additionally, there is rarely any evidence provided about the extent of implementation and sustainability of the intervention, and most studies are limited to a single hospital/health service.

Cardoso et al. included two US studies of apology laws in obstetrics.(46) A 2011 study comparing 32 states found 13% lower payments (by over $32,000) to plaintiffs in malpractice cases in states with an apology law compared to states without ($p < 0.01$).(62). A 2010 uncontrolled before and after study of the University of Michigan Health System program found that the average monthly rate of new claims declined from 7.03 to 4.52 per 100,000 patient encounters (Risk Ratio [RR] 0.64; 95% CI 0.44–0.95) and average monthly rate of lawsuits dropped from 2.13 to 0.75 per 100,000 patient encounters (RR 0.35; 95% CI 0.22–0.58) after program implementation.(63) Additionally, the median time from claim reporting to resolution decreased from 1.36 to 0.95 years, average monthly cost rates decreased for total liability (RR 0.41, 95% CI 0.26–0.66), as did patient compensation (RR 0.41, 95% CI 0.26–0.67), and non-compensation-related legal costs (RR 0.39, 95% CI 0.22–0.67).(46, 63)

Adams et al. also conducted an evaluation of the University of Michigan Health System CRP in gastroenterology.(44) Using an uncontrolled before- and- after design reported in a conference abstract, Adams reported that a total of 66 encounters resulted in claims, 38 occurring in the 10 year pre-implementation era and 28 in the 10 year post-implementation era (despite a 72% increase in clinical activity). The reduction in the proportion of encounters resulting in claims was statistically significant ($p=0.001$). There was also a trend toward reduction in the mean total incurred per claim ($167,309 pre vs. $81,107 post, $p=0.20$). The first quartile estimate of time to claim resolution for claims in the pre-implementation era was roughly twice that for claims filed in the post-implementation era (1000 vs. 460 days) ($p<0.0001$).

Potential advantages of CRP have been identified as: improved liability outcomes; decreases in the practice of defensive medicine; greater patient satisfaction; improved quality of care; and decreased stress on healthcare providers and patients after an adverse outcome.(50) In an uncontrolled before and after study in a US hospital system, LeCraw *et al.* identified a decrease in the average number of new claims filed (1.07 to 0.36, $p=0.004$), defence costs ($41,950 to $20,623 $p=.004$), settlement costs ($19,480 to $14,228 $p=0.510$), and total liability costs ($61,430 to $34,851, $p=0.022$) under a collaborative CRP (all measured per 1000 hospital admissions).(50) The median time interval to resolve a claim decreased from 17 months to eight months, a reduction of 53% ($p<0.001$). Additionally, 43% of events with medical error were resolved by apology alone, even though 60% of these patients had legal representation.

Fustino et al. implemented a systematic approach to improving patient satisfaction in paediatrics, emphasising infrastructure, feedback and transparency, education, and cultural change.(48) In this uncontrolled before and after study, patient satisfaction measured by Press-Ganey surveys improved from the 19th to the 70th percentile within five years while practice volume increased by 17.1%. Patient complaint/grievance frequency decreased 33-fold; and provider/staff engagement did not appreciably change.

Peer programs

Peer review, or the use of peer messengers, involves the provision of feedback to doctors deemed at higher risk of experiencing a patient complaint or malpractice claim from peer doctors. Three included studies evaluated the effects of a peer program on complaints. Mirzoev and Kane's literature review focused on collection of complaints, analysis of complaints data and action on the information. With respect to the last focus area, Mirzoev and Kane highlighted peer programs as successful interventions for physicians to improve action on complaints data.(52) Evidence from two uncontrolled before- and- after studies was consistent in demonstrating that approximately two thirds of at risk physicians will respond successfully to a peer program. However, the study design (uncontrolled before and after) was uniformly weak and there was little, if any, adjustments for other secular trends in claims or confounders, and no control sites. Additionally, there was rarely any evidence provided about the extent of implementation and sustainability of the intervention.

Pichert et al. conducted an uncontrolled before and after study in seven community and nine academic medical centres across the US.(7) They enlisted 178 physicians as peer messengers who conducted interventions on 373 physicians identified as high risk using the Patient Advocacy Reporting System (PARS®) tool analysis of unsolicited complaints. They found that peer messengers recognised by leaders and supported with high quality training and data, and evidence of positive outcomes were willing to intervene with colleagues. Nearly all (97%) of high risk physicians received the feedback professionally, and nearly two thirds (64%) were "responders" and improved risk scores by at least 15%. "Non-responders" scores worsened (17%) or remained unchanged (19%). Responders were more often physicians practising in medicine and surgery than emergency medicine physicians, had longer organisational tenures, and engaged in lengthier first-time intervention meetings with messengers.

Another study used the Patient Advocacy Reporting System (PARS®) to assess the impact of peer review in an uncontrolled before and after study of 548 US otolaryngologists from 140 medical practices.(6) Twenty-nine otolaryngologists with unsolicited patient complaints at the 95th percentile for volume received peer-comparative feedback (intervention letters, comparative figures and tables, and supporting documents delivered in person by trained physician peer "messengers"). Messengers were trained in common questions and challenges, practical situational skills, and confidentiality. Messengers encouraged participants to reflect on feedback materials and develop methods to address trends that emerged from unsolicited patient complaints; messengers did not make specific recommendations regarding behaviour or practice modifications.

The intervention led to an overall decrease in the number of unsolicited patient complaints following intervention ($p = 0.049$). Twenty otolaryngologists (69%) categorised as ''responders'' reduced the number of complaints an average of 45% in the first two years following intervention. Participants naturally clustered into 2 groups: ''responders'' (20/29, 69%) had at least 15% fewer unsolicited patient complaints in the first two years of follow-up, while ''non responders'' (9/29, 31%) had the same or more unsolicited patient complaints in the first two years of follow-up.

Continuing Professional Development (CPD) participation

In healthcare, Continuing Professional Development (CPD) comprises a range of activities undertaken to maintain clinical skills and knowledge, as well as competence in the delivery of patient-centred care.(64) Participation in CPD is mandatory for doctors in several countries, including

Australia and Canada, while being used to evaluate maintenance of competence in the US. While certain methods of CPD are known to be more effective (e.g., practice-based small-group learning) than others, the CPD approaches shown to have a lesser effect on practice behaviour (e.g., didactic large-group sessions) tend to dominate educational offerings and, as such, are selected more frequently by physicians than other forms of learning.(57) This review included two studies, which evaluated the effects of CPD on complaints, medico-legal claims and performance. These study designs were slightly stronger than for other intervention types, including a case control study and an aetiological study with adjustment for covariates (age, sex, internationally qualified, certification, hours worked, number of patients, practice locations). In summary, the two included studies provided evidence supporting an improvement in doctor performance and reduced rate of complaints about quality of care following CPD participation.

Wenghofer et al. investigated the aetiological relationships between prior participation in CPD and subsequent satisfactory assessments of performance in 617 Canadian physicians.(57) The majority of physicians (60%) were members of the Royal College of Physicians and Surgeons, and the remainder were members of the College of Family Physicians. The study found that participating in any CPD was associated with significantly higher odds (odds ratio [OR] = 2.5; p = 0.021) of having satisfactory assessments of performance. Additionally, physicians participating in group-based CPD activities were more likely to have satisfactory assessments than those who did not (OR = 2.4; p = 0.016). Participation in self-directed and assessment based CPD was not associated with performance.

A subsequent study also by Wenghofer's team tested for a relationship between complaints received by both Canadian physician groups and national CPD program participation using a case-control study.(9) Cases were doctors against whom a complaint had been made to the medical regulatory board by a member of the public, and the controls were doctors with no complaints. Complaints were related to physician communication, quality of care and professionalism. There was a significant relationship between participation in CPD, type of CPD and type of complaint received. Analysis indicated that doctors who reported overall participation in CPD activities were significantly less likely (OR 0.604; p = 0.028) to receive quality of care-related complaints than those who did not report participating in CPD. Additionally, participation in group-based CPD was less likely (OR 0.681; p = 0.041) to result in quality of care-related complaints.

Medical remediation programs

Remediation is the process by which a doctor's poor performance is 'remedied', which permits the doctor to return to safe practice.(65) It is formally defined as 'an intervention, or suite of interventions, required in response to assessment against threshold standards', with thresholds set by regulatory bodies (eg AHPRA in Australia) to keep patients safe.(66) Two studies published in 2014 from the UK and New Zealand assessed the effects of medical remediation programs delivered by a medical indemnity provider and a health regulator, respectively. Both studies demonstrated positive results from the programs in terms of improving performance to an acceptable standard and reducing number of events (claims, pre-claims, disciplinary and regulatory episodes). However, the case series design was uniformly weak and there was little, if any, adjustment for other secular trends in claims or confounders (such as CPD attendance), no control sites, and low numbers of participants. Additionally, there was rarely any evidence provided about the extent of implementation and

sustainability of the intervention, which was involuntary in one study. Both studies also identified that a small number of doctors (7-21%) did not engage or respond positively to medical remediation.

Lillis et al. studied the effects of a 12 month remedial education program on 24 doctors required to undergo remediation by the Medical Council of New Zealand.(8) Five doctors failed to engage with remediation and withdrew from clinical work. The program was completed by the remaining 19 doctors, of whom 13 were considered to be practising at an acceptable standard (on the basis of sequential supervisor reports) at the end of remediation. Six doctors were required to have a second performance assessment. Of these, only one was considered to be functioning at an acceptable standard.

O'Brien et al. examined outcomes for 58 doctors undergoing a clinical communication remedial program.(53) Doctors were included in the program if they were deemed at high risk of future claims based on their accrued risk history as assessed using a medical indemnity provider's membership governance system that focused on communication issues. Event data (claims, pre-claims, disciplinary and regulatory episodes) were compared before and after the remediation program, which was delivered over three days in a residential workshop. General practitioners (GPs) made up the bulk of participants (n=28, 47%). Plastic surgery (16%), surgery (14%), obstetrics and gynaecology (9%) and psychiatry (9%) made up most of the remaining specialties. The event rate pre-clinical communication program was 0.42 or one event every 2.3 member years; the event rate post program was 0.26 or one event every 3.8 years ($p<0.0001$). The data for claims alone show a reduction from 215 claims or one every 4.7 member years pre-program to 22 claims or one every ten member years post-program ($p<0.0001$). In respect of claims, four doctors accounted for 75% of claims post-program, which would imply that a small number of doctors did not benefit from the intervention.

Shared decision-making

Shared decision making is defined as "involving a patient and health care provider who work together to deliberate about the harms and benefits of two or more reasonable options, in order to choose a course of care that is ideally aligned with the patient's preferences" (p. 2)(47). It has been proposed that shared decision making may lead to fewer medico-legal claims and complaints, as these are more common when communication about risks, options and benefits is deficient.(45) However, based on two studies, including a systematic review, there is only limited evidence supporting a proposition that shared decision making leads to fewer medico-legal claims or complaints. One recent study was excluded from the review as it was set in the emergency department.(67)

Although it is only based on five studies (two qualitative studies, two case studies, one quasi-experimental study) of low overall quality, Durand *et al.'s* systematic review is the only systematic review included in Question 2.(47) The five included studies were published in the 1990s (n=1) and 2000s (n=4). The review confirmed the absence of empirical data necessary to determine the effectiveness of shared decision-making in reducing litigation. Simulated data/scenarios suggested that (i) "ignoring or failing to diagnose patient preferences, particularly when no effort has been made to inform and support understanding of possible harms and benefits, puts clinicians at a higher risk of litigation", and (ii) "documenting the use of decision support interventions in patients' notes could offer some level of medico-legal protection". Overall, the authors concluded that more research was required.

A national case vignette survey compared various levels of patient involvement, decisions and outcomes in a representative sample of Danish men.(45) The vignette described prostate specific antigen (PSA) screening with 30 versions of a mock clinical encounter, which differed in the amount of patient involvement, the decision made (to screen or not), and clinical outcomes (no cancer detected, detection of treatable cancer, and detection of non-treatable cancer). Respondents' inclination to complain about care was assessed. The urge to complain increased if the patient was excluded from decision making, or if the physician had nudged the patient to decline screening. Shared decision making resulted in the greatest reduction in complaint likelihood.(45)

Simulation training

One uncontrolled, retrospective pre-post program evaluation has assessed the effectiveness of simulation training on malpractice claims among obstetrician-gynaecologists.(56) There were 292 obstetrician-gynaecologists who had participated in simulation training from 10 medical institutions. Simulation training was conducted by a third party from 2002 to 2019 and focused on team training and crisis management rather than surgical or technical skills. Including the whole study period, the rate of claims after simulation training was 5.7 claims per 100 physician coverage years, which was significantly lower than the claim rate before simulation training of, 11.2 claims per 100 physician coverage years ($p<0.001$). The relative risk reduction in claim rates after simulation training for the full study period, the two-year period before and after simulation training, and the one-year period before and after simulation training was 49.5%, 41.2%, and 40.5%, respectively.

In Schaffer et al.'s study, attending more than one simulation session was associated with a greater reduction in claim rates.(56) Post-simulation claim rates for physicians who attended one, two, or three or more simulation sessions were 6.3, 2.1, and 1.3 claims per 100 physician coverage years, respectively ($p<0.001$). Compared with pre-simulation training, there was no significant difference in the median or mean indemnity paid, percentage of claims on which an indemnity payment was made, or median severity of injury after simulation training.

Gaps in the evidence

There are many apparent gaps in the evidence about interventions for reducing claims and complaints highlighted by this Evidence Check. The preponderance of lower quality study designs (case series) and absence of higher quality studies including randomised controlled trials is one of the largest gaps. Given that there are a number of potentially effective interventions in this space, and lack of clarity about which may be the most effective, a high quality study to compare effectiveness and costs of different approaches would be informative.

More generally, there is a lack of evidence for most types of interventions included in this review, in particular CPD participation, shared decision-making and simulation training. Additionally, there was considerable heterogeneity e.g. programs ranged from two-hour educational sessions(49) to three years(51).

The Patient Advocacy Reporting System (PARS®) was used by three studies to identify physicians at high risk of complaints.(5-7) However, all three studies were set in US hospitals and the applicability

of the approach to other countries is unclear. Further research may determine the utility of a similar system developed for Australia.

Only one study was included that evaluated the role of medical regulation delivering medical remediation programs in addressing patient complaints and claims.(8) Given the significant resources involved in medical regulation, greater involvement in research and comparison of outcomes following medical regulation interventions is warranted.

The Evidence Check identified only one study that specified whether a complaint was warranted or unwarranted (9) and no study included both to allow determination of predictors of successful interventions targeting unwarranted claims/complaints. Only two included studies reported on patient satisfaction in relation to complaints or claims.(48, 50)

Finally, a number of studies identified that interventions led to reduced claims and complaints in a majority of participants, termed as 'responders'.(6, 7) Many of the 'non-responders' dropped out of the study, or were not followed up to identify how such doctors could be most appropriately engaged in interventions to reduce claims and complaints. This small population deserves future investigation as they attract a relatively large proportion of complaints/claims and have demonstrated that they are difficult to engage using existing interventions suggesting that the development of new approaches may be required.

Discussion

Question 1

The results for the 25 included studies addressing Question 1 are summarised in Table 9. In brief, few of the reviewed patient characteristics have been shown to inform and influence patient actions regarding whether or not to make a complaint or claim against their doctor. Due to the narrative synthesis used to summarise results in the Evidence Check, it is not possible to state which of the identified 18 patient characteristics are most influential on patient actions, or if there are differences in the strength of the findings between the examined patient characteristics.

It should be noted that much of the comparative data is derived from studies with concurrent controls allowing measurement of the effect of the cases against the overall studied patient population. In all other uncontrolled studies, the applicability of the patient characteristic data to answering Question 1 is limited. Even in case-controlled studies, where statistical significance is recorded, none of the patient complainant characteristics were statistically significant, limiting the applicability of the comparative results.

Age

There are two studies which directly addressed the issue of how age influences an individual's likelihood to make a complaint or initiate a claim against their physician.(32, 42) There is a large age span when considering patients who are more likely to make a complaint (30-year period between 25 to 55 years) as compared to patients who are more likely to initiate a malpractice claim (19-year period between 30 to 49 years). This tends to suggest that patients are more hesitant when initiating legal action compared to making complaints which may be due to higher inherent institutional thresholds in terms of finance, time and emotional factors and access to justice. In addition, specific complaints are also more evident in specific age groups. For instance, in complaints relating to a physician's refusal to prescribe drugs, patients between 65 to 79 years have a higher likelihood to complain compared to people under 18 years even where the impact of such refusal is more pronounced in the younger age group.(32)

Sex

Generally, the studies are consistent in showing that female patients are more likely to make a complaint as well as initiate a claim than male patients. It has been suggested that female and male patients experience different areas of dissatisfaction and as such, make complaints and claims for different reasons. (27) For example, a greater proportion of women's complaints are reported to concern interpersonal aspects of care. In addition, women complain more than men about interaction, communication and information. However, men complained more than women about

Table 9 Summary of patient characteristics in the examined studies

Study reference ID	Age	Sex	Patient risk factors	Therapeutic context	Complain-ant	Race	Employment status	Length of stay	Complic-ation	Insurance Status	Marital Status	Education	Relationship with the clinician	Mental, behavioural and neurodevelopmental disorder
(58)				✓	✓									
(20)							✓				✓	✓		
(21)	✓	✓			✓									
(22)	✓	✓		✓										
(23)	✓	✓	✓											
(24)	✓	✓		✓										
(25)	✓	✓												
(26)	✓	✓			✓	✓								
(27)		✓			✓									
(28)	✓	✓	✓	✓	✓	✓	✓			✓				✓
(29)													✓	
(30)			✓											
(31)	✓	✓	✓		✓			✓	✓					
(32)	✓	✓					✓			✓	✓	✓		
(33)	✓	✓				✓								
(34)	✓		✓	✓										
(35)	✓	✓												
(36)	✓		✓											

Study reference ID	Age	Sex	Patient risk factors	Therapeutic context	Complain-ant	Race	Employment status	Length of stay	Complic-ation	Insurance Status	Marital Status	Education	Relationship with the clinician	Mental, behavioural and neurodevelopmental disorder
(37)	✓	✓												
(38)													✓	
(39)		✓			✓									
(40)	✓	✓	✓			✓		✓						
(42)	✓	✓	✓	✓			✓			✓				
(41)	✓	✓						✓						
(43)	✓		✓											

organisation and resources.(27) The same study found that there were no significant sex differences concerning dissatisfaction with treatment.

In addition, in complaints and claims lodged by a patient's relative, females also have a higher likelihood of initiating the complaint or claim even when they themselves are not the subject of the harm.

Patient risk factors and therapeutic context

There was little consistent evidence supporting a relationship between patient risk factors and therapeutic context and rates of claims and complaints. There was insufficient data to determine the effect of American Society of Anaesthesiologists (ASA) and BMI score on a patient's likelihood to initiate a complaint or claim. There was insufficient evidence suggesting impact of patient setting, treatment type or diagnosis on likelihood of patient complaint or claim.

Complainant, complications, race

The studies are not conclusive in informing whether specific complainants, complication, or race increase the likelihood of a patient making a complaint or claim. Each of the included studies had varied results and were not consistent in their findings. The authors postulate that these patient characteristics are very much specific to a given institution as well as geographic factors which are not addressed in the reviewed studies. In addition, the way that each study analysed the impact of these patient characteristics on patient complaints and claims differed significantly.

Employment and insurance status

The studies examining employment and insurance status as patient characteristics are generally consistent in their findings.

On employment, the studies show that patients with consistent and ongoing employment tend to have less inclination to make a complaint or initiate a claim against their physician. While no reason is directly given in the reviewed studies, Kearney et al. did also capture participant income as a secondary measure in the surveys.(32) One could postulate that financial pressure may be a factor that motivates patients who are unemployed to initiate a complaint or legal claim.

On insurance status, patients with health insurance were generally less likely to initiate a claim than those that did not hold any health insurance. As Schnitzer et al. noted, that patients who are in precarious financial situations evidenced by a lack of employment or health safety net are more likely to complain or initiate a claim against their treating physician.(42)

Length of stay

While not significant, the reviewed studies did tend to imply that patients with shorter length of stay in an in-patient hospital setting had a higher likelihood of making a complaint or initiating a claim against their treating doctor compared with patients with shorter stays.

Mental, behavioural and neurodevelopmental disorders

Assessment of mental, behavioural and neurodevelopmental disorders by Grandizio et al. was the only statistically significant patient characteristic assessed as part of a comparative case controlled study. The results show that patients with an underlying mental, behavioural, or neurodevelopmental disorders are associated with higher rates of patient complaints.(28)

Other patient factors and characteristics

Given the limited scope of evidence for the remaining patient characteristics, there is no significant indications regarding whether they have any influence on a patient's likelihood of making a complaint or initiating a legal claim against their doctor.

Question 2

The results for 20 included studies addressing Question 2 are summarised in Table 10. While results were consistent in demonstrating improvements across all outcomes, the risk of bias from the lower levels of study designs in the included studies makes an overall assessment of the body of evidence difficult. In brief, the findings of all included studies showed some benefit in improving outcomes (e.g. reducing number or amount of claims) however this must be off-set by the known limitations of such study designs that are prone to over-estimate true effect sizes.(68, 69) The result is that while the evidence base for interventions demonstrated some positive effects on outcomes, very little strength could be offered for recommendations/findings emanating from Question 2. In some ways, this replicates the results of the only included systematic review that was based on results of five non-RCTs assessing shared decision making, including two qualitative studies, two case studies and one quasi-experimental studies. This review concluded that "The analysis confirms the absence of empirical data necessary to determine whether or not shared decision-making promoted in the clinical encounter can reduce litigation" (p. 1)(47).

Due to the narrative synthesis used to summarise results in the Evidence Check, it is not possible to state which of the seven intervention types is most effective, or if there are differences in strength of findings between outcomes. As shown in Table 10, most of the included evidence is based on the number and cost of claims, number of complaints, and timeliness of claims resolution. Fewer studies have examined clinician risk profile, staff knowledge and confidence, and patient satisfaction. Impacts on culture, staff satisfaction and patient outcomes were only included in a single study.

It is important to consider to what extent these findings reflect the wider literature, including studies published before 2011 or in other settings. Generally, most recent publications are based on commentary/opinion pieces or review of legal cases, rather than empirical studies testing the effectiveness of interventions. Many are specific to types of patients or sub-specialties that provide anecdotal advice about ways of minimising the likelihood of doctors being sued for malpractice. Given that these have been excluded from the review, it is not appropriate to include them in the discussion.

There are, however, a few recently published studies that can inform greater understanding of some of the more commonly investigated intervention types (risk management programs, communication and resolution program, CPD participation, and medical remediation program).

Table 10 Summary of findings for Question 2 What initiatives or interventions have been shown to be effective at reducing complaints about the care they have received from a doctor? Each ✓ and ~ indicates a study, including the citation.

Study design	Total	↓ Claims	↓ Complaints	More timely management	↓ Claims, costs, or premiums	↓ Clinician risk profile/ ↑ performance	↑ Culture	↑ Staff knowledge / confidence	↑ Staff satisfaction	↑ Patient satisfaction	↑ Patient outcomes (less mortality or injury)
Risk management program	6	✓✓✓✓ (5, 51, 54, 55)	✓(58)	✓(58)	✓✓✓✓ (5, 51, 54, 55)		✓(51)	✓✓(49, 51)	✓(54)		✓(54)
Communication and resolution program	4	✓✓✓ (44, 46, 50)	✓(48)	✓✓✓ (44, 46, 50)	~✓✓ (44, 46, 50)					✓✓(48, 50)	
Peer program	3		✓(6)			✓(7)					
CPD participation	2		✓(9)			✓(57)					
Medical remediation program	2	✓(53)				✓(8)					
Shared decision-making	2		✓(45)								
Simulation training	1	✓(56)			~(56)						

↓ decrease ↑ increase ✓ a study reporting a better outcome (e.g. reduced claims rate) ~ a study reporting an equivalent outcome

CPD = continuing professional development

Risk management programs

Although ‘risk management programs’ was the intervention with the highest number of included studies (n=6), no recent, relevant studies were identified in a search of PubMed and Google scholar databases. This finding points to the lack of specificity of ‘risk management program’ and ‘risk reduction strategies’ as search terms, reflecting the heterogeneity apparent across the interventions in the six included studies. However, a search of publications from authors of the included studies did identify three studies that help to contextualise the findings of the Evidence Check. (70-72)

These studies report education and/or skills training for surgeons at University of Pennsylvania Health System to minimise risks of being named in a malpractice claim. In the 2015 study, the course comprised didactic lectures, video critique and provision of a toolkit to improve surgeon communication. (70) In the 2016 study, a 90 minute education package addressed five principles of medical malpractice: (i) the basics of negligent torts, the special case of medical malpractice, and the role of expert witnesses; (ii) the cost of malpractice insurance; (iii) divisional and individual risk rating based on experience points; (iv) current departmental claims experience, strategies for decreasing the risk of being named in a claim; and (v) an overview of malpractice reforms designed to make compensation for medical error more efficient. (71) The later study involved the development of a short course (60-90 minutes) on the informed consent process. (72) The curriculum comprised three parts: ethico-historical and legal principles, current requirements, and new consent developments.

Evaluation of the courses was very limited and based around post-course satisfactory scores for seven components, such as clarity of goals, or instructiveness of the legal elements, and some quizzes to test knowledge. Generally, across the three studies, the attendance rate was high (84-86%), and favourable satisfaction scores were given for most of the course components. The results highlight the importance of tailoring the course content to their state (Pennsylvania) context, due to state-specific nature of malpractice claims and legislation. For the informed consent training, the authors provided the short course materials as appendices including: a Powerpoint slide deck, facilitator guide, and evaluation. (72)These three studies support and extend findings from the Evidence Check around the acceptability of internally developed, locally-contextualised education for surgeons, in particular. Supporting and enhancing communication skills to minimise risks of complaints and claims is a focus of risk management programs. While acceptability and some improvement in knowledge were shown, there is no additional evidence provided about the effectiveness of such education in reducing complaints or claims.

Communication and resolution programs (CRP)

There are four recent studies that relate to CRPs, including apology laws.(73-76). Limited adherence to the key components of CRP “fuels scepticism that programs are meeting the needs of injured patients”.(76) Gallagher *et al.* describes two forms of selective use of CRPs. First, organisations mayavoid using CRP when patients seem unlikely to assert a malpractice claim. Second, organisations may apply some, but not all CRP practices to a given case, for example, emphasising transparent communication while withholding proactive compensation. A qualitative study identified a number of facilitators for successful implementation of CRPs at two Massachusetts hospital systems.(74) The seven facilitators were: (1) the support of top institutional leaders; (2) heavy investments in educating physicians about the program; (3) active cultivation of the relationship

between hospital risk managers and representatives from the liability insurer; (4) the use of formal decision protocols; (5) effective oversight by full-time project managers; (6) collaborative group implementation; and (7) small institutional size.

Gallagher et al. reference the Collaborative for Accountability and Improvement, based at UW School of Medicine as a provider of tools for measuring and enhancing adherence to CRP components: https://communicationandresolution.org/. The Gallagher *et al.* perspective supports the findings of this Evidence Check that the evidence base for CRPs demonstrates reductions in volume and costs of malpractice claims. However, Fields *et al.'s* viewpoint is that the evidence base on apology laws is mixed.(75) They cite a recent legal study that contradicts the belief that apology laws lead to decreased liability risk (77) while stating that "overall, McMichael and colleagues' results do not persuasively show that apology laws elevate liability risk" (p. 65).(75) Fields *et al.* conclude that while there are no clear conclusions about the liability impact of these laws, there is little cause for optimism that apology laws decrease liability risk. Ross and Newman supported this viewpoint in their analysis, and attributed the inefficacy to most US states having partial apology laws, which do not protect statements that have the desired therapeutic benefits necessary to decrease malpractice rates.(73) Partial apologies are particularly ineffective in the present of asymmetric information sharing which is common in the US health system.(73) Ensuring that apology laws can support the work of CRPs (ie by encompassing a statement of fault and explanation) and enacting full apology laws (currently only present in nine US states) may address some of the deficiencies noted above.(73, 75) Hospital-based disclosure programs, which incorporate communication training, institutional support for providers during the apology process, financial compensation and robust efforts to prevent errors from recurring, are likely to be more effective than stand-alone apology laws.(73)

CPD participation

A recently updated Cochrane Review has investigated the effects of educational meetings (as a form of CPD through courses, seminars, and workshops in various formats) on professional practice and healthcare outcomes across health professions.(3) The review included 215 studies involving more than 28,167 health professionals, including 142 new studies for the update. Physicians (GPs and specialists) were the largest group of healthcare professionals, although results are not reported separately. The review found that educational meetings probably improve professional practice (such as compliance with desired practice) and, to a lesser extent, patient outcomes (such as cholesterol levels). Educational meetings may improve compliance with desired practice to a greater extent than other kinds of behaviour change interventions, such as text messages, fees, or office systems. The authors concluded that multi-strategy approaches might positively influence the effects of educational meetings.(3) There were not enough included studies to compare interactive versus didactic meetings, or different formats and durations of meetings.

Medical remediation program

With one exception (78), recent reviews of medical remediation have addressed multiple health professions (4, 79) or both student and practising doctors (80). The Price et al. study is a substantial piece of work from an international collaborative reporting the results of a realist review of 141 included studies.(66) There were four key findings presented in the realist framework of context-mechanism-outcome configurations. These findings are: "Remediation programmes are effective

when a doctor's insight and motivation are developed and behaviour change reinforced. Insight can be developed by providing safe spaces, using advocacy to promote trust and framing feedback sensitively. Motivation can be enhanced by involving the doctor in remediation planning, correcting causal attribution, goal setting and destigmatising remediation. Sustained change can be achieved by practising new behaviours and skills, and through guided reflection" (p. 995) (78). The study findings support the use of simulation, coaches, and a cyclical approach to remediation in which changed behaviours may engender further insight into other issues.

Kennedy et al. conducted a scoping review of remediation programs for regulated health professions.(4) The aim of the scoping review was to examine the purpose, format, and outcomes of remediation programs for regulated HCPs described in the peer-reviewed and grey literature and described in written submissions by Canadian regulatory bodies. Although multidisciplinary, the majority of included studies (eight of 14) targeted physicians. They found that remediation processes were consistently identified as having at least three phases including (i) an assessment phase; (ii) an active remediation phase; and (iii) a reassessment phase.(4) Additionally, the scoping review reported agreement in the literature, and in written responses from Canadian regulatory bodies, that remediation should be targeted toward the individual requirements of the healthcare professional. Both active and passive learning methods can be used to deliver the program and engage participants.(81) Active learning strategies included in the scoping review were: mentoring, supervised skills practice, and problem-based learning. Passive learning is more didactic and is provided through lectures, e-modules and reviews.(4) Description of outcomes focused on the use of appropriate valid and reliable tools, rather than the success of programs to improve clinician competency.

Another recent multi-disciplinary systematic review on outcomes of remediation and rehabilitation programs for healthcare professionals with performance concerns included a total of 38 studies.(79) Nearly 80% of studies were published before 2010 and over three-quarters focussed on physicians. While more than half were based in the US seven of eight studies reporting on remediation outcomes for dyscompetence (or poor professional performance) were conducted in Canada. These studies showed varying levels of success. However, program completion rates for substance use disorders were positive and 80-90% of participants were employed after treatment.

The Brennan et al. review focused on remediating lapses in professionalism (for example honesty, integrity, respect and a commitment to high standards of practice) as opposed to performance deficiencies, knowledge and skills. (80) The review included studies of remediation for both medical students and practising doctors but did not report findings separately. The findings of the review were limited by a small evidence base of low quality, which "tentatively suggests that the remediation of lapses in professionalism, as part of a wider programme of remediation, can work to facilitate medical students and doctors to graduate from a programme of study and to pass medical licensing examination" (p.200) (80). However, the review also found that there was no evidence about remediation of lapses of professionalism, specifically. The included studies used, on average, three behaviour change theories. The most popular behaviour change theories were, respectively, instruction on how to perform the behaviour (19%), goal setting (18%), feedback on behaviour (15%) and problem solving (16%).(80)

These four additional studies, although mainly multi-professional, provide additional detail about the mechanisms behind successful remediation programs for doctors that are described earlier in this Evidence Check.

Conclusion

There were eighteen types of patient characteristics examined to determine likelihood of making a medico-legal complaint or initiating a claim. All of the case-controlled studies dealt with complaints rather than malpractice claims.

Of 18 types of patient characteristics that may be related to the likelihood of making a complaint or initiating a malpractice claim, none demonstrated either strength or consistency of effect. Higher patient age may be weakly correlated with greater chance of complaint; female patients or female relatives of male patients may be more likely to make complaints than male patients. However, there are few, if any, patient characteristics that can be reliably considered to be related to likelihood of complaint or claims. More prospective studies would improve the level of evidence. Additionally, many of the patient characteristics reviewed in the literature are likely to interact, requiring more elaborate study designs to clearly elucidate associations.

There were seven types of interventions studied which targeted a reduction in claims and complaints against doctors: risk management programs; communication and resolution programs; peer programs; CPD participation; medical remediation programs; shared decision-making; and, simulation training. Evidence for Question 2 is consistent across these interventions in demonstrating reduced number and associated costs of claims, reduced number of complaints, and increased timeliness of claims/complaints management. However, the strength of the evidence is very weak. It is based on study designs that are highly prone to bias, lack control groups and statistical adjustment for confounders, have low sample sizes and/or are set in a single institution, and lack evidence about program fidelity and sustainability.

The findings of this Evidence Check have been compared against recent studies that address the research questions but were excluded due to not meeting inclusion criteria for either study design (e.g. a qualitative study design) or population (e.g. a mixed population of nurses, doctors and allied health, or medical students and practising doctors) or outcome (e.g. not including an outcome of claims or complaints). Generally, the results from these recent studies support the findings of the Evidence Check and provide some assurance about the consistency of the identified relationships.

References

1. Austin EE, Do V, Nullwala R, Fajardo Pulido D, Hibbert PD, Braithwaite J, et al. Systematic review of the factors and the key indicators that identify doctors at risk of complaints, malpractice claims or impaired performance. BMJ Open. 2021;11(8):e050377. doi: 10.1136/bmjopen-2021-050377
2. Sax Institute. Evidence Check: Doctors challenges and Patient complaints. Sydney: Sax Insititute, 2022.
3. Forsetlund L, O'Brien MA, Forsén L, Mwai L, Reinar LM, Okwen MP, et al. Continuing education meetings and workshops: effects on professional practice and healthcare outcomes. Cochrane Database of Systematic Reviews. 2021(9). doi: 10.1002/14651858.CD003030.pub3
4. Kennedy G, Jacobs N, Freemark L, Madan S, Chan N, Tran Y, et al. Remediation Programs for Regulated Health Care Professionals: A Scoping Review. J Contin Educ Health Prof. 2022;42(1):36-46. doi: 10.1097/ceh.0000000000000377
5. Diraviam SP, Sullivan PG, Sestito JA, Nepps ME, Clapp JT, Fleisher LA. Physician Engagement in Malpractice Risk Reduction: A UPHS Case Study. Jt Comm J Qual Patient Saf. 2018;44(10):605-12. doi: doi:10.1016/j.jcjq.2018.03.009
6. Nassiri AM, Pichert JW, Domenico HJ, Galloway MB, Cooper WO, Bennett ML. Unsolicited Patient Complaints among Otolaryngologists. Otolaryngol Head Neck Surg. 2019;160(5):810-7. doi: doi:10.1177/0194599818823706
7. Pichert JW, Moore IN, Karrass J, Jay JS, Westlake MW, Catron TF, et al. An intervention model that promotes accountability: peer messengers and patient/family complaints. Jt Comm J Qual Patient Saf. 2013;39(10):435-46. doi: doi:10.1016/s1553-7250(13)39057-6
8. Lillis S, Takai N, Francis S. Long-Term Outcomes of a Remedial Education Program for Doctors With Clinical Performance Deficits. Journal of Continuing Education in the Health Professions. 2014;34(2):96-101. doi: doi:10.1002/chp.21227
9. Wenghofer EF, Campbell C, Marlow B, Kam SM, Carter L, McCauley W. The effect of continuing professional development on public complaints: A case-control study. Medical Education. 2015;49(3):264-75. doi: doi:10.1111/medu.12633
10. Runciman W, Merry A, Walton M. Safety and Ethics in Healthcare: A Guide to Getting it Right. Aldershot: Ashgate; 2007.
11. Grober ED, Bohnen JMA. Defining medical error. Can J Surg. 2005;48(1):39-44
12. Abdelrahman W, Abdelmageed A. Understanding patient complaints. BMJ: British Medical Journal. 2017;356
13. Bismark MM, Studdert DM. Realising the research power of complaints data. The New Zealand Medical Journal (Online). 2010;123(1314)
14. Hickson GB, Pichert JW, Webb LE, Gabbe SG. A complementary approach to promoting professionalism: identifying, measuring, and addressing unprofessional behaviors. Acad Med. 2007;82(11):1040-8. doi: 10.1097/ACM.0b013e31815761ee
15. Daniel AE, Burn RJ, Horarlk S. Patients' complaints about medical practice. MJA. 1999;170(12):598-602. doi: 10.5694/j.1326-5377.1999.tb127910.x
16. Bermingham K. More than $100m in medical malpractice claims paid out over past three years. The Advertiser. 2022 12th October.
17. Moola S, Munn Z, Sears K, Sfetcu R, Currie M, Lisy K, et al. Conducting systematic reviews of association (etiology): The Joanna Briggs Institute's approach. Int J Evid Based Healthc. 2015;13(3):163-9. doi: 10.1097/xeb.0000000000000064
18. Ouzzani M, Hammady H, Fedorowicz Z, Elmagarmid A. Rayyan—a web and mobile app for systematic reviews. Systematic Reviews. 2016;5(1):210. doi: 10.1186/s13643-016-0384-4

19. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ. 2021;372:n71. doi: 10.1136/bmj.n71
20. Birkeland S, Bismark M, Barry MJ, Möller S. Sociodemographic characteristics associated with a higher wish to complain about health care. Public Health. 2022;210:41-7. doi: doi:10.1016/j.puhe.2022.06.009
21. Bujoreanu I, Hariri A, Acharya V, Taghi A. An Analysis of Complaints in Two Large Tertiary University Teaching Hospital ENT Departments: A Two-Year Retrospective Review. Int J Otolaryngol. 2020;2020:1484687. doi: doi:10.1155/2020/1484687
22. Calder LA, Héroux DL, Bernard CA, Liu R, Neilson HK, Gilchrist AD, et al. Surgical Fires and Burns: A 5-Year Analysis of Medico-legal Cases. Journal of Burn Care and Research. 2019;40(6):886-92. doi: doi:10.1093/jbcr/irz108
23. Calder LA, Whyte EM, Neilson HK, Zhang C, Barry TK, Barry SP. Trends and Contributing Factors in Medicolegal Cases Involving Spine Surgery. Spine. 2022;47(11):E469-E76. doi: doi:10.1097/BRS.0000000000004332
24. Coysh T, Breen DP. A nationwide analysis of successful litigation claims in neurological practice. JRSM Short Reports. 2014;5(3):1-3. doi: doi:10.1177/2042533313518914
25. Crosbie C, McDougall A, Pangli H, Abu-Laban RB, Calder LA. College complaints against resident physicians in Canada: a retrospective analysis of Canadian Medical Protective Association data from 2013 to 2017. CMAJ Open. 2022;10(1):E35-e42. doi: doi:10.9778/cmajo.20210026
26. Elias RM, Fischer KM, Siddiqui MA, Coons T, Meyerhofer CA, Pretzman HJ, et al. A Taxonomic Review of Patient Complaints in Adult Hospital Medicine. J Patient Exp. 2021;8:23743735211007351. doi: doi:10.1177/23743735211007351
27. Eriksson EM, Raharjo H, Gustavsson S. Exploring complaints by female and male patients at Swedish hospitals using a probabilistic graphical model. Scand J Caring Sci. 2018;32(3):1148-56. doi: 10.1111/scs.12560
28. Grandizio LC, Barreto Rocha DF, Piper JP, Hayes DS, Klena JC. An Analysis of Formal Patient Complaints and Malpractice Events Involving Hand and Upper Extremity Surgeons. J Am Acad Orthop Surg. 2021;29(15):659-65. doi: doi:10.5435/jaaos-d-21-00073
29. Harrison R, Walton M, Healy J, Smith-Merry J, Hobbs C. Patient complaints about hospital services: applying a complaint taxonomy to analyse and respond to complaints. Int J Qual Health Care. 2016;28(2):240-5. doi: 10.1093/intqhc/mzw003
30. Hawdon JM, Beer J, Sharp D, Upton M. Neonatal hypoglycaemia: learning from claims. Arch Dis Child Fetal Neonatal Ed. 2017;102(2):F110-F5. doi: 10.1136/archdischild-2016-310936
31. Jones K, Davies B, Stubbs DJ, Komashie A, Burnstein RM, Hutchinson P, et al. Can compliment and complaint data inform the care of individuals with chronic subdural haematoma (cSDH)? BMJ Open Qual. 2021;10(3). doi: doi:10.1136/bmjoq-2020-001246
32. Kearney L, Concannon E, Rolle C, Hynes M, Malesevic V, Kelly JL. Influence of socioeconomic factors on litigation in surgery: Addressing the gap in malpractice literature. J Plast Reconstr Aesthet Surg. 2020;73(2):376-82. doi: doi:10.1016/j.bjps.2019.09.030
33. Kynes JM, Schildcrout JS, Hickson GB, Pichert JW, Han X, Ehrenfeld JM, et al. An analysis of risk factors for patient complaints about ambulatory anesthesiology care. Anesth Analg. 2013;116(6):1325-32. doi: doi:10.1213/ANE.0b013e31827aef83
34. Lefebvre G, Devenny KA, Héroux DL, Bowman CL, Neilson HK, Mimeault R, et al. Intraoperative injuries from abdominopelvic surgery: An analysis of national medicolegal data. Can J Surg. 2021;64(2):E127-E34. doi: doi:10.1503/cjs.010219
35. McSweeney W, Leaning M, Dastouri D, Parkinson D, Hendahewa R. It's not you, it's me: a descriptive study of patient complaints and surgeon understanding. ANZ Journal of Surgery. 2021;91(10):1991-5. doi: doi:10.1111/ans.17033
36. Nowotny BM, Loh E, Davies-Tuck M, Hodges R, Wallace EM. Using patient factors to predict obstetric complaints and litigation: A mixed methods approach to quality improvement. Journal of Patient Safety and Risk Management. 2018;23(5):185-99. doi: doi:10.1177/2516043518799020
37. O'Connell RL, Patani N, Machin JT, Briggs TWR, Irvine T, MacNeill FA. Litigation in breast surgery: unique insights from the English National Health Service experience. BJS open. 2021;5(3). doi: doi:10.1093/bjsopen/zraa068

38. Oyebode F. Clinical errors and medical negligence. Med Princ Pract. 2013;22(4):323-33. doi: doi:10.1159/000346296
39. Reader TW, Gillespie A, Roberts J. Patient complaints in healthcare systems: a systematic review and coding taxonomy. BMJ Qual Saf. 2014;23(8):678-89. doi: 10.1136/bmjqs-2013-002437
40. Rennie JM, Beer J, Upton M. Learning from claims: hyperbilirubinaemia and kernicterus. Arch Dis Child Fetal Neonatal Ed. 2019;104(2):F202-F4. doi: 10.1136/archdischild-2017-314622
41. Robin Taylor D, Bouttell J, Campbell JN, Lightbody CJ. A case-controlled study of relatives' complaints concerning patients who died in hospital: The role of treatment escalation/limitation planning. Int J Qual Health C. 2020;32(3):212-8. doi: 10.1093/intqhc/mzaa008
42. Schnitzer S, Kuhlmey A, Adolph H, Holzhausen J, Schenk L. Complaints as indicators of health care shortcomings: which groups of patients are affected? Int J Qual Health C. 2012;24(5):476-82. doi: 10.1093/intqhc/mzs036
43. Vilos GA, Ternamian A, Vilos AG, Abu-Rafea B, Zhu CC. Direct Laparoscopic Trocar Insertion: Lessons Learned from Nine Litigated Cases. J Minim Invas Gyn. 2017;24(6):960-70. doi: 10.1016/j.jmig.2017.05.014
44. Adams MA, Elmunzer BJ, Scheiman JM. Effect of a health system's medical error disclosure program on gastroenterology-related claims rates and costs. Am J Gastroenterol. 2014;109(4):460-4. doi: doi:10.1038/ajg.2013.375
45. Birkeland S, Bismark M, Barry MJ, Möller S. Does greater patient involvement in healthcare decision-making affect malpractice complaints? A large case vignette survey. PLoS ONE. 2021;16(7). doi: doi:10.1371/journal.pone.0254052
46. Cardoso R, Zarin W, Nincic V, Barber SL, Gulmezoglu AM, Wilson C, et al. Evaluative reports on medical malpractice policies in obstetrics: a rapid scoping review. Syst Rev. 2017;6(1):181. doi: doi:10.1186/s13643-017-0569-5
47. Durand MA, Moulton B, Cockle E, Mann M, Elwyn G. Can shared decision-making reduce medical malpractice litigation? A systematic review. BMC HEALTH SERVICES RESEARCH. 2015;15. doi: doi:10.1186/s12913-015-0823-2
48. Fustino NJ, Moore P, Viers S, Cheyne K. Improving Patient Experience of Care Providers in a Multispecialty Ambulatory Pediatrics Practice. Clin Pediatr (Phila). 2019;58(1):50-9. doi: doi:10.1177/0009922818806309
49. Juo YY, Lewis C, Hanna C, Reber HA, Tillou A. An Innovative Approach for Familiarizing Surgeons with Malpractice Litigation. J Surg Educ. 2019;76(1):127-33. doi: doi:10.1016/j.jsurg.2018.06.002
50. LeCraw FR, Montanera D, Jackson JP, Keys JC, Hetzler DC, Mroz TA. Changes in liability claims, costs, and resolution times following the introduction of a communication-and-resolution program in Tennessee. Journal of Patient Safety and Risk Management. 2018;23(1):13-8. doi: 10.1177/1356262217751808
51. Milne JK, Walker DE, Vlahaki D. Reflections on the Canadian MORE(OB) obstetrical risk management programme. Best Pract Res Clin Obstet Gynaecol. 2013;27(4):563-9. doi: 10.1016/j.bpobgyn.2013.02.008
52. Mirzoev T, Kane S. Key strategies to improve systems for managing patient complaints within health facilities - what can we learn from the existing literature? Global Health Action. 2018;11(1). doi: 10.1080/16549716.2018.1458938
53. O'Brien M, Dinwoodie M, Hartwig B, Blaney D. The Clinical Communication Program: an effective intervention for reducing future risk for high-risk physicians. ASIA PACIFIC JOURNAL OF HEALTH MANAGEMENT. 2014;9(1):8-13. doi: doi:
54. Pegalis SE, Bal BS. Closed medical negligence claims can drive patient safety and reduce litigation. Clin Orthop Relat Res. 2012;470(5):1398-404. doi: doi:10.1007/s11999-012-2308-5
55. Raper SE, Rose D, Nepps ME, Drebin JA. Taking the Initiative: Risk-Reduction Strategies and Decreased Malpractice Costs. J Am Coll Surg. 2017;225(5):612-21. doi: doi:10.1016/j.jamcollsurg.2017.07.1070
56. Schaffer AC, Babayan A, Einbinder JS, Sato L, Gardner R. Association of Simulation Training With Rates of Medical Malpractice Claims Among Obstetrician-Gynecologists. Obstet Gynecol. 2021;138(2):246-52. doi: 10.1097/aog.0000000000004464
57. Wenghofer EF, Marlow B, Campbell C, Carter L, Kam S, McCauley W, et al. The Relationship Between Physician Participation in Continuing Professional Development Programs and

Physician In-Practice Peer Assessments. Acad Med. 2014;89(6):920-7. doi: 10.1097/Acm.0000000000000243
58. Barragry RA, Varadkar LE, Hanlon DK, Bailey KF, O'Dowd TC, O'Shea BJ. An analytic observational study on complaints management in the general practice out of hours care setting: who complains, why, and what can we do about it? BMC Family Practice. 2016;17(1):87. doi: 10.1186/s12875-016-0484-1
59. National Health and Medical Research Council. NHMRC levels of evidence and grades for recommendations for guideline developers. Canberra: National Health and Medical Research Council, 2009.
60. Liu J, Hyman DA. The impact of medical malpractice reforms. Annual Review of Law and Social Science2020. p. 405-19.
61. Agarwal R, Gupta A, Gupta S. The impact of tort reform on defensive medicine, quality of care, and physician supply: A systematic review. Health Services Research. 2019 2019/08//:851+.
62. Ho B, Liu E. What's an Apology Worth? Decomposing the Effect of Apologies on Medical Malpractice Payments Using State Apology Laws. Journal of Empirical Legal Studies. 2011;8(s1):179-99. doi: https://doi.org/10.1111/j.1740-1461.2011.01226.x
63. Kachalia A, Kaufman SR, Boothman R, Anderson S, Welch K, Saint S, et al. Liability claims and costs before and after implementation of a medical error disclosure program. Annals of internal medicine. 2010;153(4):213-21. doi: 10.7326/0003-4819-153-4-201008170-00002
64. Royal Australasian College of Physicians. Continuing Professional Development (CPD) Participation Policy. Sydney: RACP, 2020.
65. Price T, Archer J. UK Policy on Doctor Remediation: Trajectories and Challenges. The Journal of continuing education in the health professions. 2017;37(3):207-11. doi: 10.1097/CEH.0000000000000167
66. Price T, Brennan N, Wong G, Withers L, Cleland J, Wanner A, et al. Remediation programmes for practising doctors to restore patient safety: the RESTORE realist review. Health Services and Delivery Research. 2021;9(11):1-116. doi: 10.3310/hsdr09110
67. Schoenfeld EM, Mader S, Houghton C, Wenger R, Probst MA, Schoenfeld DA, et al. The Effect of Shared Decisionmaking on Patients' Likelihood of Filing a Complaint or Lawsuit: A Simulation Study. Ann Emerg Med. 2019;74(1):126-36. doi: doi:10.1016/j.annemergmed.2018.11.017
68. Cuijpers P, van Straten A, Bohlmeijer E, Hollon SD, Andersson G. The effects of psychotherapy for adult depression are overestimated: a meta-analysis of study quality and effect size. Psychological Medicine. 2010;40(2):211-23. doi: 10.1017/S0033291709006114
69. Schäfer T, Schwarz MA. The Meaningfulness of Effect Sizes in Psychological Research: Differences Between Sub-Disciplines and the Impact of Potential Biases. Front Psychol. 2019;10:813-. doi: 10.3389/fpsyg.2019.00813
70. Raper SE, Gupta M, Okusanya O, Morris JB. Improving Communication Skills: A Course for Academic Medical Center Surgery Residents and Faculty. Journal of Surgical Education. 2015;72(6):e202-e11. doi: https://doi.org/10.1016/j.jsurg.2015.06.008
71. Raper SE, Joseph J, Seymour WG, Sullivan PG. Tipping the scales: educating surgeons about medical malpractice. J Surg Res. 2016;206(1):206-13. doi: 10.1016/j.jss.2016.08.002
72. Raper SE, Joseph J. Informed Consent for Academic Surgeons: A Curriculum-Based Update. MedEdPORTAL. 2020;16:10985. doi: 10.15766/mep_2374-8265.10985
73. Ross NE, Newman WJ. The Role of Apology Laws in Medical Malpractice. J Am Acad Psychiatry Law. 2021;49(3):406-14. doi: 10.29158/jaapl.200107-20
74. Mello MM, Roche S, Greenberg Y, Folcarelli PH, Van Niel MB, Kachalia A. Ensuring successful implementation of communication-and-resolution programmes. BMJ Qual Saf. 2020;29(11):895. doi: 10.1136/bmjqs-2019-010296
75. Fields AC, Mello MM, Kachalia A. Apology laws and malpractice liability: What have we learned? BMJ Qual Saf. 2021;30(1):64-7. doi: 10.1136/bmjqs-2020-010955
76. Gallagher TH, Mello MM, Sage WM, Bell SK, McDonald TB, Thomas EJ. Can communication-and-resolution programs achieve their potential? Five key questions. Health Affairs. 2018;37(11):1845-52. doi: 10.1377/hlthaff.2018.0727
77. McMichael BJ, Van Horn RL, Viscusi WK. "Sorry" Is Never Enough: How State Apology Laws Fail to Reduce Medical Malpractice Liability Risk. Stanford law review. 2019;71(2):341-409

78. Price T, Wong G, Withers L, Wanner A, Cleland J, Gale T, et al. Optimising the delivery of remediation programmes for doctors: A realist review. Medical Education. 2021;55(9):995-1010. doi: https://doi.org/10.1111/medu.14528
79. Weenink JW, Kool RB, Bartels RH, Westert GP. Getting back on track: a systematic review of the outcomes of remediation and rehabilitation programmes for healthcare professionals with performance concerns. BMJ Qual Saf. 2017;26(12):1004-14. doi: 10.1136/bmjqs-2017-006710
80. Brennan N, Price T, Archer J, Brett J. Remediating professionalism lapses in medical students and doctors: A systematic review. Medical Education. 2020;54(3):196-204. doi: https://doi.org/10.1111/medu.14016
81. Prescott-Clements L, Voller V, Bell M, Nestors N, van der Vleuten CPM. Rethinking Remediation: A Model to Support the Detailed Diagnosis of Clinicians' Performance Problems and the Development of Effective Remediation Plans. J Contin Educ Health Prof. 2017;37(4):245-54. doi: 10.1097/ceh.0000000000000173

Appendices

Appendix 1. Search strategy

Pubmed search

Search number	Query	Filters	Results
1	"medical officer*"[Title/Abstract] OR "doctor*"[Title/Abstract] OR "physician*"[Title/Abstract] OR "medicine"[MeSH Terms] OR "health service"[Title/Abstract]		1,744,081
2	"malpractice"[Title/Abstract] OR "negligen*"[Title/Abstract] OR "patient complaint*"[Title/Abstract] OR "closed claim*"[Title/Abstract] OR "open claim*"[Title/Abstract] OR "claim manage*"[Title/Abstract] OR "malpractice"[MeSH Terms] OR "insurance, liability"[MeSH Terms] OR "professional misconduct"[MeSH Terms] OR "medical defence*"[Title/Abstract] OR "medical regulat*"[Title/Abstract] OR "medicolegal*"[Title/Abstract] OR "medico legal*"[Title/Abstract] OR "medical errors"[MeSH Terms]		178,858
3	"patient characteristic*"[Title/Abstract] OR "demograph*"[Title/Abstract] OR "sociodemograph*"[Title/Abstract] OR "medical histor*"[Title/Abstract] OR "socio economic*"[Title/Abstract] OR "SES"[Title/Abstract] OR "patient factor*"[Title/Abstract] OR "risk factor*"[Title/Abstract] OR "patient attribute*"[Title/Abstract] OR "health literacy"[Title/Abstract] OR "health literacy"[MeSH Terms]		1,277,476
4	"evidence based care bundle"[Title/Abstract] OR "patient care bundles"[MeSH Terms] OR "simulation training"[Title/Abstract] OR "simulation training"[MeSH Terms] OR "patient safety"[Title/Abstract] OR "patient safety"[MeSH Terms] OR "safety checklist*"[Title/Abstract] OR "standardisation"[Title/Abstract] OR "standardization"[Title/Abstract] OR "communication"[Title/Abstract] OR "health communication"[MeSH Terms] OR "teamwork"[Title/Abstract] OR "crew resource management, healthcare"[MeSH Terms] OR		415,299

	"handover"[Title/Abstract] OR "clinical handover"[Title/Abstract] OR "patient handoff"[MeSH Terms]		
5	"Medical education"[Title/Abstract] OR "education, medical, continuing"[MeSH Terms] OR "risk mitigation"[Title/Abstract] OR "risk management"[Title/Abstract] OR "risk management"[MeSH Terms] OR "empathy training"[Title/Abstract] OR "empathy"[MeSH Terms] OR "Informed consent training"[Title/Abstract] OR "informed consent"[MeSH Terms] OR "open disclosure"[Title/Abstract]		486,923
6	#4 or #5		873,547
7	#3 or #6		2,067,502
8	#1 and #2 and #7		9,319
9	#1 and #2 and #7	English	8,454
10	#1 and #2 and #7	English, from 2011 - 2023	4,108

Scopus search

Search number	Query	Filters	Results
1	"medical officer*" OR "doctor*" OR "physician*" OR "health service"		1,771,700
2	malpractice OR "negligen*" OR "patient complaint*" OR "closed claim*" OR "open claim*" OR "claim manage*" OR "malpractice" OR "medical defence*" OR "medical regulat*" OR "medicolegal*" OR "medico legal*" OR "medical errors" OR "professional misconduct"		135,232
3	"patient characteristic*" OR "demograph*" OR "sociodemograph*" OR "medical histor*" OR "socio economic*" OR "SES" OR "patient factor*" OR "risk factor*" OR "patient attribute*" OR "health literacy"		3,053,434

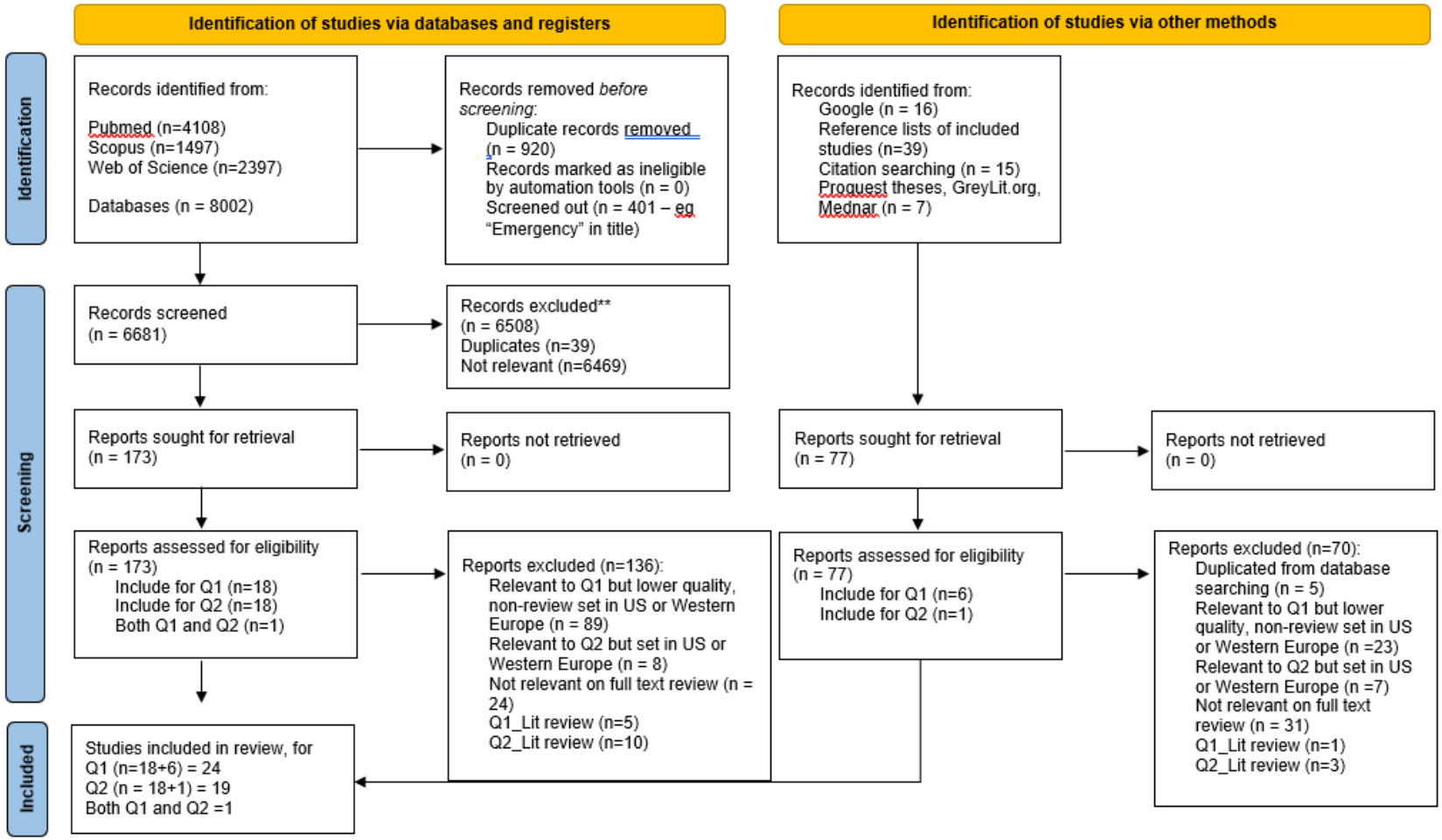
4	"evidence based care bundle" OR "patient care bundles" OR "simulation training" OR "patient safety"OR "safety checklist*"OR "standardisation" OR "standardization" OR "communication" OR "teamwork" OR "crew resource management" OR "handover" OR "patient handoff"		2,683,446
5	"Medical education" OR "risk mitigation" OR "risk management" OR "empathy training" OR "informed consent" OR "open disclosure"		558,386
6	#4 or #5		3,176,929
7	#3 or #6		6,095,114
8	#1 and #2 and #7		14,994
9	#1 and #2 and #7	limit English	13,621
10	#1 and #2 and #7	limit English, >2010	5,879
		limit AU, NZ, CA, UK	1497

Web of Science

Search number	Query	Filters	Results
1	medical officer* OR doctor* OR physician* OR health service		923305
2	malpractice OR negligen* OR patient complaint* OR closed claim* OR open claim* OR claim manage* OR malpractice OR medical defence* OR medical regulat* OR medicolegal* OR medico legal* OR medical errors OR professional misconduct		209988
3	patient characteristic* OR demograph* OR sociodemograph* OR medical histor* OR socio economic* OR SES OR patient factor* OR risk factor* OR patient attribute* OR health literacy		3341468
4	evidence based care bundle OR patient care bundle* OR simulation training OR patient safety OR safety checklist* OR standardisation OR standardization OR communication OR teamwork OR crew resource management OR handover OR patient handoff		1852131
5	Medical education OR risk mitigation OR risk management OR empathy training OR informed consent OR open disclosure		775393
6			2549833
7			5457457
8			18061

9		limit English	16582
10		limit English, >2010	11431
		limit AU, NZ, CA, UK	2397

Appendix 2. PRISMA flowchart



Appendix 3. Evidence grading

Level of Evidence	Study Design
I	A systematic review of Level II studies
II	A randomised controlled trial
III-1	A pseudo-randomised controlled trial (i.e., alternate allocation or some other method)
III-2	A comparative study with concurrent controls (i.e. non-randomised experimental trials, cohort studies, case-control studies, interrupted time series studies with a control group)
III-3	A comparative study without concurrent controls (i.e. historical control study, two or more single arm studies, interrupted time series studies without a parallel control group)
IV	Case series with either post-test or pre-test/post-test outcomes

Source: National Health and Medical Research Council (2009) ***NHMRC levels of evidence and grades for recommendations for guideline developers.*** Canberra: National Health and Medical Research Council. Available from: https://www.nhmrc.gov.au/_files_nhmrc/file/guidelines/developers/nhmrc_levels_grades_evidence_120423.pdf

Appendix 4. Data extraction tables

Table A-1. Characteristics of included studies for Question 1

First author (year) Study reference ID	Design NHMRC	Design 'if other'	Country	Setting	Specialty	Condition	Type	Warranted or unwarranted	Patient characteristics
Barragry (2016)(58)	Other[@]	Cross-sectional analysis of patient complaints from multiple general practices	Ireland	Primary care	General practice	Mixed	Complaint	n/s	Complainant, setting
Birkeland (2022)(20)	Other	Survey	Denmark	Primary care	Primary care	Prostate cancer (survey)	Mix	Unwarranted	Marital status, education, current employment, chronic illness, experience with the medical condition, population density, tax per citizen, race
Bujoreanu (2020)(21)	Other	Cross-sectional analysis of patient complaints	UK	In-patient hospital	Ear nose and throat	Mixed	Mix	n/s	Age, sex, complainant, who they reported to i.e. nursing, administrative,

First author (year) Study reference ID	Design NHMRC	Design 'if other'	Country	Setting	Specialty	Condition	Type	Warranted or unwarranted	Patient characteristics
		from one hospital							management or other healthcare staff.
Calder (2019)(22)	Other	Cross-sectional analysis of closed claims from national database	Canada	In-patient hospital	Mixed	Mixed	Complaint	n/s	Age, sex, setting
Calder (2022)(23)	Other	Cross-sectional analysis of closed claims from national database	Canada	In-patient hospital	General surgery	Mixed	Mix	n/s	Age, sex, ASA score, risk factors (obesity/previous spinal surgery), patient indicators for spinal surgery, treatment
Coysh (2014)(24)	Other	Cross-sectional analysis of closed claims from national database	UK	In-patient hospital	Mixed	Neurological	Malpractice litigation	n/s	Age, sex, patient disease group
Crosbie (2022)(25)	Other	Cross-sectional analysis of	Canada	Mixed	Mixed	Mixed	Regulatory	n/s	Age, sex

First author (year) Study reference ID	Design NHMRC	Design 'if other'	Country	Setting	Specialty	Condition	Type	Warranted or unwarranted	Patient characteristics
		patient complaints from national database							
Elias (2021)(26)	Other	Cross-sectional analysis of patient complaints from one hospital	US	In-patient hospital	Mixed	Mixed (hospital wide)	Complaint	n/s	Age, sex, race, region, complainant
Eriksson (2018)(27)	Other	Cross-sectional analysis of patient complaints from multiple hospitals	Sweden	In-patient hospital	Mixed	Mixed	Complaint	both	Sex, complainant
Grandizio (2021)(28)	A comparative study with concurrent controls	-	US	Mixed	Hand surgery	Hand surgery	Complaint	n/s	Age, sex, BMI>30, race, marital status, employment status, tobacco use, and insurance status, type of disorder, diagnosis, treatment, complications

First author (year) Study reference ID	Design NHMRC	Design 'if other'	Country	Setting	Specialty	Condition	Type	Warranted or unwarranted	Patient characteristics
Harrison (2016)(29)	Other	Cross-sectional analysis of patient complaints from national database	Australia	In-patient hospital	Mixed	Mixed	Complaint	n/s	Relationship with the clinician
Hawdon (2017)(30)	Other	Cross-sectional analysis of closed claims from national database	UK	Mixed	Neonatal	Neonatal hypoglycaemia	Malpractice litigation	Warranted	Risk factors, treatment
Jones (2021)(31)	A comparative study with concurrent controls	-	UK	In-patient hospital	Neurosurgery	Chronic subdural haematoma (cSDH)	Complaint	n/s	Age, sex, complainant, ASA score, referred from other hospital, LOS, time from admission to operation, reoperation, in-hospital complication
Kearney (2020)(32)	Other	Survey	Ireland	In-patient hospital	Surgery	Surgical	Malpractice litigation	n/s	Age, sex, marital status, income, educational background, number of dependents, employment status and insurance status

First author (year) Study reference ID	Design NHMRC	Design 'if other'	Country	Setting	Specialty	Condition	Type	Warranted or unwarranted	Patient characteristics
Kynes (2013)(33)	A comparative study with concurrent controls	-	US	In-patient hospital	Anaesthesiology	Mixed	Complaint	n/s	Age, sex, race
Lefebvre (2021)(34)	Other	Cross-sectional analysis of closed claims from national database	Canada	In-patient hospital	Abdominopelvic surgery	Abdominopelvic conditions	Mix	n/s	Age, BMI, previous surgery, ASA score, surgery acuity, treatment
McSweeney (2021)(35)	Other	Cross-sectional analysis of patient complaints from one hospital	Australia	Mixed	General surgery	n/s	Complaint	n/s	Age, sex, and mode of presentation
Nowotny (2018)(36)	Other	Retrospective mixed methods study of a convenience sample of all births in	Australia	In-patient hospital	Maternity	Pregnancy	Mix	n/s	Age, country of birth, spoken language, hospital of birth, risk factors (e.g. pre-existing maternal medical conditions, parity)

First author (year) Study reference ID	Design NHMRC	Design 'if other'	Country	Setting	Specialty	Condition	Type	Warranted or unwarranted	Patient characteristics
		a large health service							
O'Connell (2021)(37)	Other	Cross-sectional analysis of closed claims from national database	UK	In-patient hospital	Breast surgery	Mixed	Malpractice litigation	n/s	Age, sex
Oyebode (2013)(38)	Other	Systematic review of non-RCTs or literature review	-	In-patient hospital	Mixed	Mixed	Malpractice litigation	n/s	Relationship with the clinician
Reader (2014)(39)	Other	Systematic review of non-RCTs or literature review	-	Mixed	Mixed	Mixed	Complaint	n/s	Sex, complainant
Rennie (2019)(40)	Other	Cross-sectional analysis of closed claims from	UK	Mixed	Neonatal	Neonatal jaundice	Malpractice litigation	Warranted	Age, sex, weight, race, patient indicators (e.g. blood group, antibody, history), LOS, treatment

First author (year) Study reference ID	Design NHMRC	Design 'if other'	Country	Setting	Specialty	Condition	Type	Warranted or unwarranted	Patient characteristics
		national database							
Schnitzer (2012)(42)	Other	Cross-sectional analysis of patient complaints from national database	Germany	Mixed	u/k	n/s	Complaint	n/s	Age, sex, insurance status, region, employment, chronic disease, multimorbidity
Robin Taylor (2020)(41)	A comparative study with concurrent controls	-	UK	In-patient hospital	Medical and surgical wards	End of life	Complaint	n/s	Age, sex, expected death, los, advance plans
Vilos (2017)(43)	Other	Cross-sectional analysis of closed claims from national database	Canada	In-patient hospital	Laparoscopic surgery with direct trocar insertion	Mixed	Malpractice litigation	Both	Age, BMI

[@] - Study design refers to Question 1 results, a different study design was used for Question 2

Acronyms: ASA – American Society of Anaesthesiologists; BMI – Body Mass Index; LOS – length of stay. u/k - unknown, n/a - not applicable, n/s - not specified.

Table A-2. Characteristics of included studies for Question 2

First author (year) Study reference ID	Design NHMRC	Design 'if other'	Country	Setting	Specialty	Condition	Type	Warranted or unwarranted	Intervention type
Adams (2014)(44)	Case series	-	US	In-patient hospital	Gastroenterology	Gastrointestinal diseases	Malpractice litigation	n/s	Communication and resolution program
Barragry (2016)(58)	Case series@	-	Ireland	Primary care	General practice	Mixed	Complaint	n/s	Risk management program
Birkeland (2021)(45)	Other	Survey	Denmark	Primary care	Primary care	Cancer	Complaint	n/s	Shared decision-making
Cardoso (2017)(46)	Other	Systematic review of non-RCTs or literature review	US	Secondary care (specialist)	Obstetrics	Obstetrics and gynaecology	Malpractice litigation	n/s	Communication and resolution program
Diraviam (2018)(5)	Case series	-	US	In-patient hospital	Mixed	Mixed	Malpractice litigation	n/s	Risk management program
Durand (2015)(47)	A systematic review of Level II studies	Systematic review or literature review	-	Mixed	Mixed	Mixed	Malpractice litigation	n/s	Shared decision-making

First author (year) Study reference ID	Design NHMRC	Design 'if other'	Country	Setting	Specialty	Condition	Type	Warranted or unwarranted	Intervention type
Fustino (2019)(48)	Case series	-	US	In-patient hospital	Mixed	Mixed	n/a	n/s	Communication and resolution program
Juo (2019)(49)	Case series	-	US	In-patient hospital	General surgery	n/a	Malpractice litigation	n/s	Risk management program
LeCraw (2018)(50)	Case series	-	US	In-patient hospital	Mixed	Mixed	Malpractice litigation	n/s	Communication and resolution program
Lillis (2014)(8)	Case series	-	New Zealand	Mixed	Mixed	n/a	Regulatory	n/s	Medical remediation program
Milne (2013)(51)	Case series	-	Canada	In-patient hospital	Mixed	Obstetrics and gynaecology	Malpractice litigation	n/s	Risk management program
Mirzoev (2018)(52)	Other	Systematic review of non-RCTs or literature review	UK	Mixed	n/s	u/k	Complaint	n/s	Peer program
Nassiri (2019)(6)	Case series	-	US	In-patient hospital	Otolaryngology	u/k	Complaint	n/s	Peer program

First author (year) Study reference ID	Design NHMRC	Design 'if other'	Country	Setting	Specialty	Condition	Type	Warranted or unwarranted	Intervention type
O'Brien (2014)(53)	Case series	-	UK	Mixed	Mixed	n/a	Mix	n/s	Medical remediation program
Pegalis (2012)(54)	Other	Systematic review of non-RCTs or literature review	US	Mixed	Mixed	u/k	Malpractice litigation	n/s	Risk management program
Pichert (2013)(33)	Case series	-	US	In-patient hospital	Mixed	u/k	Complaint	n/s	Peer program
Raper (2017)(55)	Case series	-	US	In-patient hospital	General surgery	Surgical	n/a	n/s	Risk management program
Schaffer (2021)(56)	Case series	-	US	In-patient hospital	Obstetrics and gynecology	Obstetrics and gynaecology	Malpractice litigation	n/s	Simulation training
Wenghofer (2014)(57)	Other	Aetiological study	Canada	Mixed	Mixed	n/a	n/a	n/s	CPD participation
Wenghofer (2015)(9)	A comparative study with concurrent controls	-	Canada	Mixed	Mixed	n/a	Complaint	Warranted	CPD participation

@ - Study design refers to Question 2 results, a different study design was used for Question 1

Acronyms: CPD – Continuing Professional Development. u/k - unknown, n/a - not applicable, n/s - not specified.