Title: A systematic review of patient complaints about general practice

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Key Messages

1. Clinical and safety issues are prevalent in general practice complaints.

2. Patients can be motivated to complain to improve quality of care.

3. Further research on reliably coding general practice complaints is required.

Abstract

Background: Healthcare complaints are an underutilised resource for quality and safety improvement. Most research on healthcare complaints is focused on secondary care. However, there is also a need to consider patient safety in general practice, and complaints could inform quality and safety improvement.

Objective: This review aimed to synthesise the extant research on complaints in general practice.

Methods: Five electronic databases were searched; Medline, Web of Science, CINAHL, PsycINFO, and Academic Search Complete. Peer-reviewed studies describing the content, impact of, and motivation for complaints were included, and data extracted. Framework synthesis was conducted using the Healthcare Complaints Analysis Tool (HCAT) as an organising framework. Methodological quality was appraised using the Quality Assessment Tool for Studies with Diverse Designs (QATSDD).

Results: The search identified 2,960 records, with 21 studies meeting inclusion criteria. Methodological quality was found to be variable. The contents of complaints were classified using the HCAT, with 126 complaints (54%) classified in the Clinical domain, 55 (23%) classified as Management, and 54 (23%) classified as Relationships. Motivations identified for making complaints included quality improvement for other patients, and monetary compensation. Complaints had both positive and negative impacts on individuals and systems involved.

Conclusion: This review highlighted the high proportion of clinical complaints in general practice compared to secondary care, patients' motivations for making complaints, and the positive and negative impacts that complaints can have on healthcare systems. Future research focused on the reliable coding of complaints, and their use to improve quality and safety in general practice, is required.

Keywords: Access to Care, Community Medicine, Doctor-Patient Relationship, Medical Errors/ Patient Safety, Primary Care, Quality of Care

Background

Healthcare complaints are formal expressions of dissatisfaction regarding any action or care by the health service or a healthcare provider that is perceived to be sub-optimal and to have an adverse impact on patients and their families(1). The submission of a complaint indicates that a threshold of dissatisfaction has been crossed during the process of care(2).

Healthcare complaints are recognised as an underutilised resource for quality and safety improvement(3). Complaints are traditionally addressed on an individual basis, typically by responding to the patient and resolving the issue identified in that specific complaint(4). However, there is recognised value to analysing complaints at the systems level by aggregating the data from multiple complaints and utilising the learning from this process(5,6). Patients often have insight into issues and problems that providers themselves do not recognise or are not exposed to (e.g., problems prior to admission and following discharge)(7). The knowledge gained from patient complaints could be particularly important when a culture exists in a system whereby staff are unwilling or unable to raise quality and safety issues themselves(8).

Most research on healthcare complaints is focused on care delivered in the hospital setting(6). This is unsurprising, given that the study of safety and quality in general practice lags far behind that in hospital settings(9). Typically, general practice has been considered relatively low-risk(10). However, as services are increasingly being diverted from a hospital setting to the community(11,12), there is a greater need to consider quality and safety in this domain of healthcare. Patients interact more frequently with their General Practitioner (GP) than hospital doctors(13,14), and with this increase in volume of interaction, the risk of errors occurring also rises(15). Adverse events have been found to occur in 2-3% of general practice appointments(16). However, despite the recognition of the growing complexity and potential

for error in general practice, GPs report that they find it difficult to know where to start with implementing quality and safety improvement practices(17).

Healthcare complaints could serve as one source of data for informing quality and safety improvement in general practice. Serious issues occur in general practice which patient complaints could identify, such as treatment delays, difficulty accessing treatment, or delays in diagnosis(18). Using complaints to access patient insights into safety and quality issues in general practice could provide valuable learning, given the frequency of contact and the privileged viewpoint that patients have within the healthcare system(7).

This systematic review aimed to synthesise the extant research on healthcare complaints and medicolegal claims in general practice. Medicolegal claims are defined as a written demand for compensation for medical injury(19), and complaints are formal expressions of dissatisfaction with healthcare(1). For the purpose of this review, both will be hereafter referred to using the umbrella term “complaints”. Specifically, we examined the following: a) the content of complaints described in included studies; b) what motivated the individual to make the complaint; c) the impact of the complaints on the healthcare providers and systems involved, and; d) the harm experienced by the patients in the incident which led to the complaint. It was intended that this review would offer an understanding of the nature and impact of healthcare complaints in general practice, and facilitate comparison between the content of healthcare complaints in primary and secondary care. The review also considers the potential for adapting existing complaints taxonomies to make these more readily applicable to general practice.

Method

This systematic review was conducted with reference to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines(20). In accordance with best practice in systematic reviews(21), a protocol for the review was registered on the Prospective Register of Systematic Reviews (PROSPERO; registration number CRD42019123245).

Search strategy

Five electronic databases were screened to identify relevant papers for inclusion in this review: Medline, Web of Science, Academic Search Complete, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and PsycINFO, between October and November 2018, and updated in March 2019. The search strategy was developed with the assistance of a research support librarian, and was based on the strategy used by Reader and colleagues(6). The search comprised of Medical Subject Headings (MeSH terms) and other keywords relating to patient safety or experience (e.g., "patient satisfaction", "safe*"), complaints (e.g., "malpractice", "complain*"), and primary care (e.g., "general practice", "primary care"). The full electronic search strategy used for Medline can be found in Supplementary Data 1. This search strategy was adapted as necessary for the other electronic databases. The search strategy included terms relating to healthcare practitioners and services other than general practice (e.g., dentistry, physiotherapy, pharmacy), as this review was part of a larger community care-focused project. However, for the purposes of this review, the authors only included studies that focused on general practice. In each database, search returns were limited to English language results only. There was no limit placed upon publication year. Following the electronic searches, the reference lists of studies which were identified as suitable for inclusion, and those of related review papers(6,22), were screened to

identify any additional relevant studies. This search strategy complied with best practice for systematic reviews, as laid out in the Assessing the Methodological Quality of Systematic Reviews (AMSTAR) checklist(23).

Study selection

Inclusion criteria

To be eligible for inclusion, studies were required to be peer-reviewed and to present original, empirical data on healthcare complaints that related to poor care experiences in general practice. Studies were required to have a focus on one or more of the following: 1) patients' motivation for making the complaint; 2) the content or nature of complaints; 3) the impact of the complaint on the patient, healthcare provider or system, or: 4) the harm experienced by patients in the event leading to the complaint. For the purposes of this review, it was considered necessary that the complaints described within studies were instigated by the patient/service user, or someone acting on their behalf, rather than being solicited by researchers through surveys, interviews, or otherwise.

Exclusion criteria

Studies that were focused on healthcare complaints relating to secondary care settings were excluded along with studies which provided no original, empirical data on healthcare complaints (e.g., review papers, editorials, or commentaries). Studies were also excluded if: 1) they were focused on the analysis of incident reports from healthcare professionals; 2) complaints were solicited using a survey or qualitative methodology, and; 3) they focused on community health services other than general practice.

Screening process

The title and abstract of all search returns in each of the five databases were screened by the first author (EOD). The full-text of any study that appeared relevant was screened in order to confirm its suitability for inclusion. Further, if it was unclear from examination of the title and the abstract whether or not the study fit the inclusion criteria, the full text of the article was also screened. A second author (SL) reviewed any article for which there remained uncertainty.

Data extraction and synthesis

Data extraction was conducted independently by two authors (EOD and CM). Any disagreements were resolved through discussion until consensus was achieved. Agreement was calculated as an average of 95% across all studies, ranging from 89% to 100% for individual studies. A third author (SL) was consulted in the event that consensus could not be achieved. A standardised form was used by the two authors to extract data from studies which fit the inclusion criteria. Extracted information included general characteristics of studies (e.g., year of publication, country of study, individual making the complaint, methods used), along with the data under the headings below.

Methodological quality

The Quality Assessment Tool for Studies with Diverse designs (QATSDD)(24), was used to assess the methodological rigour of the included studies. This tool was considered appropriate as the studies included in this review were heterogeneous in design. The QATSDD is a 16-item scale developed for use by health service researchers, which has been used successfully in other systematic reviews(25-27). Each QATSDD item is scored on a scale ranging from 0 (e.g., 'no mention at all') to 3 (e.g., 'detailed description of each stage of the data collection procedure'), with a maximum possible score of 42 for qualitative or

quantitative studies, and 48 for mixed method studies. Two authors (EOD and CM) applied the QATSDD to included studies, and disagreements were resolved through discussion until consensus was achieved.

Content and categorisation of complaints

Data on the content of complaints (i.e., the issue(s) described) were extracted from the studies. These data took the form of raw complaints extracted from either text or tables within the included studies, and/or the interpretations of complaints made by the authors of individual studies. These data were synthesised by four authors (EOD, SL, POC, CM) using the Healthcare Complaints Analysis Tool (HCAT)(28). The HCAT is a tool which allows for the systematic coding and categorisation of healthcare complaints in a hospital setting(28). The HCAT has been found to be statistically reliable and valid, and there is no suitable tool designed specifically for use in general practice. A framework synthesis approach was taken to coding the complaints with the HCAT. Framework synthesis is a structured, deductive approach to collating data, often used when there is an existing theory(29). Data were coded into the HCAT framework using an iterative process. This allowed for the researchers to determine how the general practice complaints can fit under the HCAT tool, which was developed for hospital complaints. Complaints were categorised using domains ('Clinical', 'Management', 'Relationships') and categories within those domains such as "Quality", "Safety", "Listening" and "Environment".

Motive for making complaint

If available, information on the reason(s) why the patient was motivated to make a complaint was extracted.

Impact of complaint

Where possible, the impact of the complaint on the patient, providers, or healthcare service was extracted from studies.

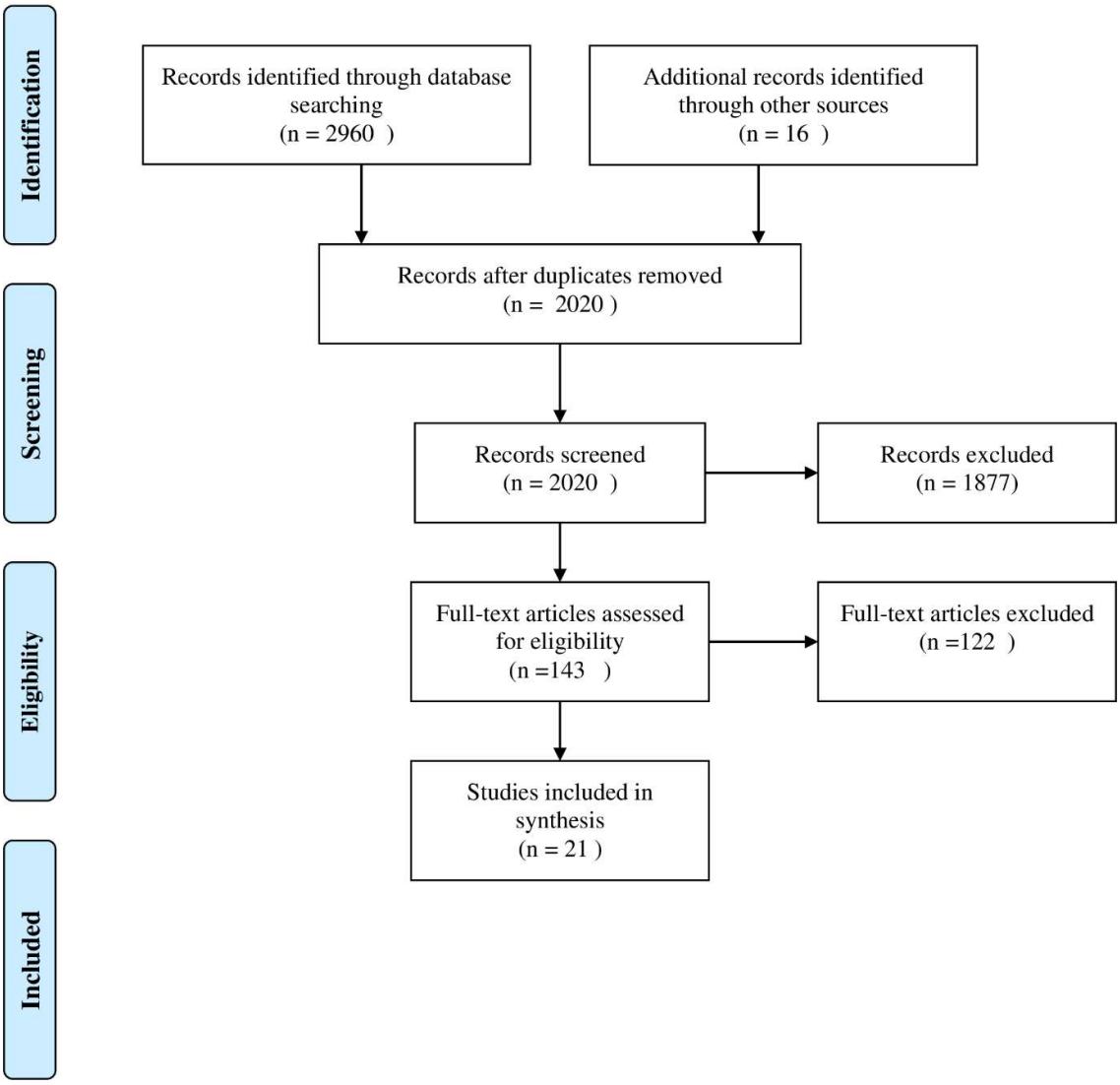
Harm to patient in events leading to complaint

When available, the harm caused to patient in the event leading to the complaint was extracted.

Results

A total of 2,960 records were identified from the databases screened, with further papers identified from hand searches of reference lists. Figure 1 presents the PRISMA flow diagram. A total of 21 papers(19,30-49), published between 1986 and 2018, were deemed eligible for inclusion in the review.

Figure 1. PRISMA Flow Diagram



Methodological quality (*n*=21)

Overall, the quality of included studies was found to be variable, with 14 studies scoring 50% or less (raw score of 24 or less) on the QATSDD (mean raw score =19.8, range of scores =8-29). One study was qualitative only, six were quantitative only, and 14 were mixed methods. Studies scored well on items including "Fit between stated research question and method of data collection", "Clear description of research setting", and "Statement of

aims/objectives in main body of report". Studies received low scores on items including "Evidence of sample size considered in terms of analysis", "Rationale for choice of data collection tool(s)", and "Good justification for analytical method selected".

Characteristics of included studies (*n*=21)

Table 1 presents a summary of the characteristics of studies that were included in this review. The majority were conducted in the USA (*n*=8, 38%). Studies were also conducted in countries including the UK (*n*=6, 29 %), Ireland (*n*=2, 10%) and Denmark (*n*=2, 10%). All studies took place in general practice settings, but varying terminology was used to describe these. As can be seen in Table 1, "General Practice" was the most commonly used term (*n*=14, 67%), amongst others (e.g., "ambulatory care" (*n*=2, 10%) and "family medicine" (*n*=1, 5%)). There was some variation in the characteristics of individuals who made the complaints or claims. However, in the majority of the included studies, the complaints were made either by the patient themselves (*n*=12, 57%), or by a family member (*n*=10, 48%). Finally, studies utilised different methods to examine the complaints, including reviews of complaints databases (*n*=15, 71%), observational studies with before/after designs (*n*=1, 5%), and audits of informal complaints procedures (*n*=1, 5%). Further information regarding the characteristics of included studies can be found in Supplementary Data 2.

Table 1. Characteristics of included studies (dated 1986-2018)

Characteristics	n, %
Country	
- USA	8, 38%
- UK	6, 29%
- Ireland	2, 10%
- Denmark	2, 10%
- Netherlands	1, 5%
- Israel	1, 5%
- Singapore	1, 5%
Setting	
- General practice	14, 67%
- Out of hours general practice	2, 10%
- Ambulatory care	2, 10%
- Outpatient chronic pain management	1, 5%
- Family medicine	1, 5%
- Outpatient general medicine	1, 5%
*Individual making complaint**	
- Patient	12, 57%
- Family members (including parent, son/daughter)	10, 48%
- Non-family members	4, 19%
- Partner of patient	3, 14%
- Professional colleague	3, 14%
- Solicitors/advocates	1, 5%
- Healthcare inspector	1, 5%
- Social worker	1, 5%
- Warden of sheltered housing	1, 5%
- Other	3, 14%
- Not specified	8, 38%
Method used	
- Review of claims/complaints database	15, 71%
- Analytic observational study with before/after design	1, 5%
- Audit of medical records	1, 5%
- Description of experience of handling complaints	1, 5%
- Analysis of informal complaints made to a family health service authority	1, 5%
- Audit of an informal complaints procedure	1, 5%
- Retrospective cohort study of patient complaints to an out of hours service provider	1, 5%
Motive for making complaint	
- Wish for explanation	1, 5%
- Wish for placement of responsibility	1, 5%
- Wish for quality improvement for future patients	2, 10%
- Review of GPs competence	1, 5%
- Economic compensation	1, 5%
- Better level of general service	1, 5%
- Professional discipline	1, 5%
- Feeling devalued	1, 5%
- Other sanction	1, 5%

*Column does not sum to 100% as some studies had more than one type of complainant.

Content of complaints (*n*=18)

The content of complaints was synthesised using the HCAT framework. The existing HCAT framework did not require adaptations in order to code and synthesise the content of complaints in included studies. Figure 2 presents how the complaints (*n*=235) were organised into different categories using the HCAT framework. Of the total number of complaints, 54% (*n*=126) were categorised as Clinical, 23% (*n*=55) were categorised as Management, and 23% (*n*=54) were categorised as Relationships. Exemplar complaints that were synthesised using the HCAT framework can be found in Table 2.

Figure 2: Number of complaints in included studies as classified into HCAT domains and categories (Total complaints *n*=235)

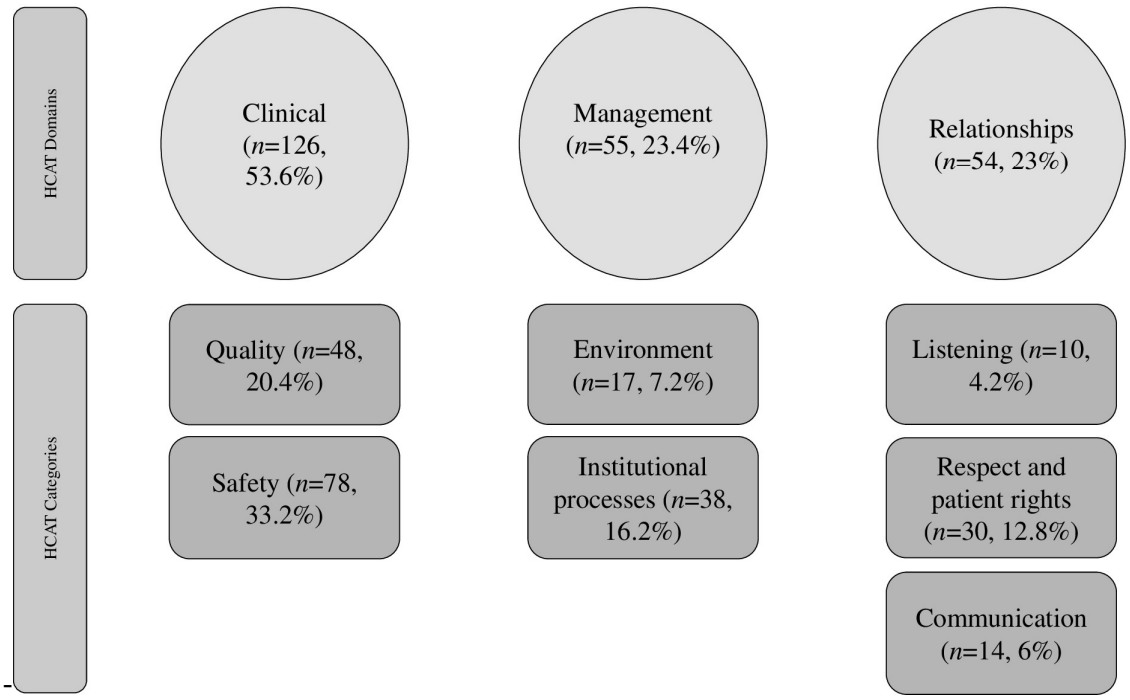


Table 2. Exemplar complaints from included studies (dated 1986-2018) categorised under Healthcare Complaints Analysis Tool

HCAT Domain *HCAT Category*	**Exemplar complaints from included studies (n)**
Clinical Problems	
Quality	Inadequate patient assessment(29) Failure to supervise or monitor care(36) Unsatisfactory treatment(43) Problems with records(45)
Safety	Wrong patient or body part(45) Misdiagnosis(43) Drug allergy missed(41) Incorrect interpretation of diagnostic or laboratory tests(38)
Management	
Environment	Physical environment(41) Telephone system(46) Poor administration(44) Inadequate disposal of drugs(43)
Institutional processes/Health system processes	Length of NHS waiting lists for treatment(46) Surgery cancelling appointments(43) Patient access to care(39) Cost(30)
Relationship	
Respect and patient rights	Alleged assault(40) Impolite behaviour(37) Breach of confidentiality(36) Discrimination(49)
Listening	Not taken seriously(43) Unmet patient expectations/requests(41) Doctor not investigating symptoms as much as the patient wanted(40)
Communication	Inadequate explanation(41) Poor explanation of illness and of prescription(30) Inadequate explanation of diagnosis or management plan(49) Poor spoken English(43)

Motives for making complaint (*n*=2)

Two of the included papers(33,44) described patients' motives for making a complaint. Motivations included a desire for placement of responsibility, economic compensation, and professional disciplining of the practitioner involved. In both studies, "preventing the same thing happening to other people" or "quality improvement for future patients" also emerged.

Impact of the complaints (*n*=16)

Studies described a number of outcomes of healthcare complaints for the patient, providers, and wider health service. At an individual patient level, the award of monetary compensation was described in four papers (19%). Other outcomes included an apology or explanation being provided to the patient (*n*=4, 19%), or the patient changing doctors (*n*=3, 14%).

A number of outcomes were described for healthcare providers in included studies, such as the disciplining of doctors (*n*=5, 24%), or complaints against them being dropped (*n*=9, 43%). Disciplinary measures included reprimands, fines, or removal from performers list.

System level outcomes such as an investigation by an external body (e.g., committee, ombudsman, governmental department), (*n*=4, 19%) and the implementation of an intervention or audit (*n*=2, 10%) were also described in some of the included studies. Further detail of the impact of complaints can be found in the data extraction table in Supplementary Data 2.

Harm to patients in events leading to complaints (*n*=14)

Of the included studies, 14 (67%) made some attempt to classify the harm to the patients in the event leading to the complaint. There was heterogeneity in the classification of harm across the included studies, however it typically ranged from “minor temporary harm”, “insignificant injury”, through to “grave injury” or death of a patient, depending on the scale that was used for classification. The National Association of Insurance commissioners severity scale (ranging from 1 ‘Emotional only’, to 9 ‘Death’)(50) was utilised in four papers (19%). Other studies developed severity scales(42), or adopted other systems(49) to measure level of harm.

Discussion

There is an increasing recognition of the importance of assessing, and improving, quality and safety in general practice. Healthcare complaints are an under-utilised data source for informing such efforts. This review examined the content of complaints in included studies, the motive and harm which led to making these complaints, and the impact of the complaints on patients, providers, and the wider system. Key findings included the fact that there was a higher proportion of clinical complaints compared to relationship or management issues, that patients can be motivated to complain with the intent of making service improvements, and that complaints had positive and negative impacts for all those involved in the process.

A large proportion of complaints in the included studies were found to focus on quality and safety issues. In the past, issues around error and safety in primary care and general practice have been somewhat neglected, with the focus being on quality and safety in secondary care(9). However, the data from this review emphasise that greater attention must be given to addressing safety in general practice. Many of the complaints in this review

related directly to clinical issues, which included errors, poor care, and safety incidents (e.g., 'Drug allergy missed'(41), 'Failure to supervise or monitor care'(37)). Patient expectations could have some role to play in these findings, particularly with regards to quality complaints, as healthcare has moved to a more consumer-based model(51-54). However, patient expectations aside, it is evident from this synthesis that safety issues must be considered more seriously in general practice research.

The proportion of general practice complaints in the included studies which related to quality and safety was greater than has been found in a review of secondary care complaints (53.6% in general practice as compared to 33.7% in secondary care(6)). This somewhat surprising result could be because patients have more frequent contact with GPs than hospital doctors, and are increasingly seeing multiple GPs(55). Lack of continuity in GP care has been flagged by practitioners as a factor leading to error (55). It is evident, therefore, that there should be increased focus on complaints relating to safety issues in general practice research. Currently, complaints data in general practice is severely underutilised as a means of identifying issues(3). Using this aggregated data, rather than addressing individual complaints, could allow researchers to develop a broader understanding of what patients are complaining about, and enable these to be addressed at a higher level, contributing to system-level organisational learning(56). GPs are competent in developing solutions to address problems around safety and quality in their own practice(15,57), and should be encouraged to examine these problems using their complaints data. However, the large body of complaints data could also be used to move beyond that, placing more emphasis on changing the system wide problems as well as individual practices(6).

Only two papers discussed the motives that led to patients making a complaint, and as such, there are limits to the conclusions that can be drawn. However, the fact that one of these motives was to improve the healthcare experience for other patients warrants further

discussion. Motives including “wish for quality improvement for future patients”(33) and “to prevent the same thing happening to other people”(44) were identified in the two studies that examined this aspect of complaints. While complaints are often viewed by practitioners as negative, and individuals who made these complaints are sometimes distrusted in their motives(58,59), this review indicates that patients can desire to be agents for change. Complaints are one way through which patients and family members can feel they are contributing to service improvement(7). It has previously been identified that patients have a privileged viewpoint within the health system, which could help increase understanding on systemic issues that occur during the process of care(56). For example, in this synthesis, complaints around institutional processes were often regarding ‘blind spots’ that only patients could identify, such as not being able to access appointments(43), or the cost of an appointment being a barrier to accessing healthcare(31). Future research should focus on exploring patients’ motivations for complaining, and engage with their wish to contribute through using complaints data, and other tools such as patient surveys.

The focus of this review was on complaints made by patients. However, there is also likely a proportion of patients who may be dissatisfied with their GP care, but do not complain. Previous research has found that people might not complain for reasons including power imbalances, lack of understanding of the complaint channels, and a lack of responsiveness on the part of the provider(60). It is important therefore for GPs to proactively engage with patients who already complain, and remove the barriers which may prevent others from complaining. For example, practitioners could ensure patients receive clear information on where to complain(60). The availability of this information would be an effective way of improving patient experience, quality, and safety, and could ensure that the viewpoints of all patients are represented(56,61,62).

The data synthesised in this review on the impact of complaints highlighted how complaints can have positive and negative impacts on the system as a whole, not just on individuals. Only two of the included studies reported practices making changes following the analysis of complaints(31,34). Included studies more often described the impact of complaints on the patient themselves, for example "payment to patient"(37), or "changing doctor"(43), and on the provider involved in the events leading to complaints such as "disciplinary action"(33), or "complaint successfully defended"(49). This focus on the negative impacts of complaints on individuals is reflected in how complaints are often framed as punitive, causing stress, anger, and even depression for the providers(58). However, potentially more important is how complaints can impact positively on the system, as a learning tool for safety improvement (e.g., 'engaging in risk reduction'(31)). Reframing complaints as learning opportunities, and analysing them collectively, could benefit practices, and also the healthcare system as a whole, by moving away from complaints as a negative experience targeting individual providers(6,63).

Limitations

There are a number of limitations to the current review. First, the studies included were heterogeneous in nature. They used different methods (e.g., review of database, audit of medical records, retrospective cohort study), categorised complaints in a variety of ways (e.g., HCAT, systems developed by the authors), and focused on different outcome variables (e.g., impact, motive, content). This heterogeneity is both a limitation and a strength. The heterogeneity increased the complexity of synthesising the data, and, as a result, it was challenging to derive learning from the data. On the other hand, this variation served to clarify the need for a reliable and standardised system for analysing GP complaints moving forward. Inclusion of a wide range of studies allowed for a broad overview of the existing

research on complaints about GP. By highlighting the heterogeneity within the canon of knowledge on complaints, this review has set the stage for future work to focus on more specific research questions. There was also considerable variation in the methodological quality of the included studies.

Secondly, raw complaints from the included studies were unavailable. Therefore, the synthesis of complaints is based upon the study authors' interpretations of the complaints rather than on the actual patient complaints. However, in most cases, the authors of included studies did provide examples of the raw data, which facilitated the synthesis.

Thirdly, it was initially intended to examine the frequency of GP complaints. This intention was included in the PROSPERO protocol. However, during the data extraction it became apparent that it was not possible to synthesise the data on frequency given the different methods authors used to calculate and present this data. As a result, it was necessary to amend the PROSPERO protocol. It is therefore recommended that some consistency is established for calculating and presenting frequency data in future studies, at which point this could be reviewed.

Finally, this review only included studies which were peer-reviewed and published in English. There is a lack of best-practice guidelines for searching grey literature, and it is often difficult to interpret data included in grey literature due to poor reporting(64). There is also some evidence to demonstrate that limiting the language does not negatively impact a review(65).

Future research and application to practice

This review has highlighted areas for future research and changes to practice. First, the use of the HCAT as an organising framework for synthesis has indicated that it can be successfully used to classify general practice complaints. However, future work is necessary

to validate the tool in primary care. The use of a standardised tool that is reliable and valid would reduce the heterogeneity of data available on complaints, and facilitate quality and safety improvements in general practice(28). Standardisation in the analysis of complaints would also facilitate comparisons between the different aspects of healthcare (such as primary and secondary care) regarding quality and safety(56). Utilising a standardised, reliable tool such as the HCAT could enable future research to apply the rigour of secondary care to the analysis of general practice complaints.

Secondly, there is a relative lack of research on complaints in general practice, as compared to secondary care. Moreover, the existing research is predominately limited to the UK and USA, and more research into GP complaints internationally is required to allow for further comparisons. This review of general practice complaints included 21 papers, compared to the 59 included in the hospital care review by Reader and colleagues(6). This finding is at odds with the high volume of contact that patients experience with general practice, indicating a need for more research on general practice complaints.

Thirdly, more research is required on how patients can contribute to improving safety and quality in general practice. It is evident from this review that patients are motivated to improve the healthcare system at large, and therefore, integrating patients' experiences must be prioritised in patient safety research moving forward.

Finally, there is a need for the learning from this systematic review to be applied by GPs to their work. The small number of practices utilising the complaints data to make system improvements indicate that this is an area to be further explored. By collating complaints and framing them as learning opportunities, GPs could use them to identify improvements and reduce the number of complaints they receive(15,57).

Conclusion

The data which emerged from this review highlighted the high proportion of quality and safety related complaints in general practice, patients' motivations to improve the healthcare system, and the various positive and negative impacts that complaints can have on individuals and systems involved. Future research focused on the reliable coding of complaints, and their use to improve quality and safety in general practice would be of much interest.

Declarations/acknowledgements

Ethical Approval: Not applicable

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Conflicts of interest: None

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Table 2. Exemplar complaints from included studies (dated 1986-2018) categorised under Healthcare Complaints Analysis Tool

HCAT Domain *HCAT Category*	**Exemplar complaints from included studies (n)**
Clinical Problems	
Quality	Inadequate patient assessment(29) Failure to supervise or monitor care(36) Unsatisfactory treatment(43) Problems with records(45)
Safety	Wrong patient or body part(45) Misdiagnosis(43) Drug allergy missed(41) Incorrect interpretation of diagnostic or laboratory tests(38)
Management	
Environment	Physical environment(41) Telephone system(46) Poor administration(44) Inadequate disposal of drugs(43)
Institutional processes/Health system processes	Length of NHS waiting lists for treatment(46) Surgery cancelling appointments(43) Patient access to care(39) Cost(30)
Relationship	
Respect and patient rights	Alleged assault(40) Impolite behaviour(37) Breach of confidentiality(36) Discrimination(49)
Listening	Not taken seriously(43) Unmet patient expectations/requests(41) Doctor not investigating symptoms as much as the patient wanted(40)
Communication	Inadequate explanation(41) Poor explanation of illness and of prescription(30) Inadequate explanation of diagnosis or management plan(49) Poor spoken English(43)

Supplementary Data 1. Summary of Medline OVID search strategy

1. Exp Patient Safety/
2. Exp Patient Satisfaction/
3. Exp Professional-Patient Relations/
4. safe*.ti,ab
5. satisf*.ti,ab
6. quality.ti,ab
7. experience*.ti,ab
8. OR/1-7
9. ((claim* or complain* or complim* or litigation or malpractice or letter* or feedback or comment*) adj3 (user* or patient* or resident* or client*)).ti,ab.
10. 8 AND 9
11. Primary Health care/
12. Home Health Nurses/
13. Medicine, Community/
14. Health Services, Outpatient/
15. Health Centres, Ambulatory/
16. Nursing, Community Health/
17. Psychiatry, Community/
18. Neighborhood Health Centers/
19. Dentistry, Community/
20. Nursing, Public Health/
21. Home Health Care Nursing/
22. Dentistry, Public Health/
23. Family adj1 Physician*.ti,ab
24. Family adj1 Pract*.ti,ab
25. Generalist*.ti,ab
26. General adj1 Pract*.ti,ab
27. Primary adj1 Care adj1 Physician*.ti,ab
28. Ambulatory adj1 Care.ti,ab
29. Primary adj1 health*.ti,ab
30. Primary adj1 health adj1 care.ti,ab
31. Primary adj1 care.ti,ab
32. office adj1 visit*.ti,ab
33. house adj1 call*.ti,ab
34. aftercare.ti,ab
35. community adj1 health adj1 nurs*.ti,ab
36. home adj1 treat*.ti,ab
37. community adj1 psychiatrist*.ti,ab
38. community adj1 psychologist*.ti,ab
39. practice adj1 nurs*.ti,ab
40. public adj1 health adj1 nurs*.ti,ab
41. dietician.ti,ab
42. dentist*.ti,ab
43. community adj1 dentist*.ti,ab

44. physiotherapist*.ti,ab
45. occupational adj1 therapist*.ti,ab
46. speech adj2 language adj1 therapist*.ti,ab
47. podiatrist.ti,ab
48. community adj1 pharmacist.ti,ab
49. OR/11-48
50. 10 AND 49

Supplementary Data 2. Data extraction table

Author, year, Country	Setting	Individual complained/ claimed against	Individual making complaint	Motive for making complaint	Content of complaint	Method	Impact of complaint/Harm	QATSDD Score
Abrecht et al, 2017, USA	Outpatient chronic pain management	Physicians	Not specified	Not specified	Behaviour-related patient factors: - Non-compliance with treatment plan - Failure to complete the scheduled follow-up appointments and tests Behaviour-related provider factors: - Sexual misconduct Clinical judgement factors: - Inadequate patient assessment - Improper selection of therapy and inadequate monitoring Communication factors: - Inadequate communication among providers - Poor rapport with the patient - Inadequate education of the patient regarding risks of treatment Documentation factors: - Insufficient, inaccurate, or delayed documentation Technical problem factors: - Pharmacy dispensing error - Medication product malfunction	Review of claims/complaints database	Harm: National Association of insurance commissioners severity scale. - "High severity" scores of 6-9 corresponding to permanent major injury or death (48.6%) - "Medium severity" 3-5 temporary major or permanent minor injuries (16.2%) - "Low severity" 0-2 – temporary minor injury (35.2%) Outcomes of the alleged damaging events included death, emotional trauma, addiction to opioids, vision loss, and other	23

					Electronic health record factors: - User error with implementation of new system Administrative factors: - Inadequate training of staff Improper medication management Abandonment Failure to diagnose Sexual misconduct Discrimination Other Defamation Wrong procedure			
Barragry et al, 2016, Ireland	Out of hours general practice	Established GP non-established GPs GP registrars	Patient themselves family members (of which 60% were mothers of minors) non-family members	Not specified	Concerns regarding clinical care Cost Communication Process of care Other Communication difficulties - Difficulty seeking information - Perceived rudeness in the consultation - Perceived lack of understanding or concern - Poor explanation of illness and of prescription	Analytic observational study, with before/after design.	Impact: - Co-operative engaged in a process of organised risk reduction. - Two complaints were the subject of a medical council investigation, neither of which were upheld, and a third complaint resulted in the Co-Operative engaging as a co-complainant with the original complainant to the general medical council in the united kingdom. The registration of the doctor was subsequently endorsed.	21

							- In the minority of cases where an adverse medical outcome was evident, the Co-operative engaged closely with the complainant, and was seen to evidently modify case handling/procedure, to actively feedback to co-operative team members involved in care, and in two instances to forward modest costs (<1500 euro, directly to complainants without prejudice, where adjudged appropriate and necessary in the light of additional expenses and inconvenience to the complainants. - In no instances did complaints relating to care of patients result in civil litigation. Harm: - In 90% of complaints overall, there were no adverse medical outcomes.	
Birkeland, dePont Christensen,	General Practice	General Practitioners	Not specified	Not specified	Not specified	Review of claims/complaints database	Impact: - Discipline of GP(s) taken in 114 (27%) of cases.	19

Damsbo et al, 2013 (a), Denmark								
Birkeland, depont Christensen et al 2013(b), Denmark	General Practice	General Practitioners	Not specified	Categorised as: Patient's wish for: **Communication:** Explanation, placement of responsibility, **Correction:** quality-improvement for future patients, review of the GP's competence, **Restoration:** economic compensation, better level of general service, **Sanction:** professional discipline, other sanction.	Not specified	Review of claims/complaints database	Impact: - GP disciplined in 126 (22%) of complaints. - Criticism expressed in 96 decisions (17%), and professional competence disputed in 30 decisions (5%). - 96 decisions resulting in the GP being criticised included eight GPs being disciplined with injunction. One of these GPs was brought before the prosecuting authority, but the charge was later dropped. Harm: - Serious urgent illness? (No/Yes) - Cancer? (No/Yes) - Death of patient? (No/Yes)	22
Cowan & Wilson, 2007, UK	Primary care	General practitioners Doctor working for an out-of-hours	Relative of patient Partner of patient Solicitors/advocates Professional Colleague	Not specified	Clinical care - Failure/delay/wrong diagnosis - prescription problem or error - inadequate or inappropriate treatment - failure to visit or delay in visit	Review of claims/complaints database	Impact: - Of 116 complaints in the sample, only evidence of three having conducted a significant event audit (SEA).	21

		primary care organisation	Other		- failure or delay in referral or inappropriate referral Interpersonal skills - Attitude or rudeness of doctor - Attitude or rudeness of nurse or admin staff - General concerns about communication Administrative problems - Record keeping - Failure to follow practice policies/procedures Professional conduct matters - Breach of confidentiality - Chaperoning problems - Consent problems		Harm: - 116 complaints after the death of a patient.	
Cox & Holden, 2009, UK	Primary Care trust, 35 GP practices	General Practitioners	Patients	Not specified	Not specified	Review of complaints/claims database	Impact: - Of the 27 GPs, management of seven affected their performers list status, one GP was removed from the performers list, one was suspended and later removed, one left general practice during the process, one remains on long-term ill-health, two GPs refusing appraisal received 28 day warning of removal from the performers list, and one received a written warning	14

							regarding list status and future behaviour. - One local GP referred for health and performance issues was also found not to be on any PCT performers list due to an administrative error. Excluding the first four, the other 23 GPs whose cases were managed by the group are known to be working as GPs today, all of whom in unrestricted practice. - There was outside involvement and support in management of the 37 cases. Remedying work was undertaken solely within the PCT in 14 cases, and shared with another body in a further 12 cases. 11 needed remedying or management outside the PCT. Harm: - Cases presented in terms of classification of performance issues according to type and risk to patients: 19/37 classified as red-light	

							risk, and 18/37 as amber.	
Esmail, 2010, UK	Primary care	General practitioners	Patients	Not specified	Failure or delay in diagnosis Medication prescription errors Failure or delay in referral Failure to ward off or recognise the side-effects of medication	Review of claims/complaints database	Severity: - The most common recorded outcome of such errors was the death of the patient (21% of cases). - Deterioration in clinical condition (6%) - unnecessary pain (4%)	15
Flannery et al, 2010, USA	Family medicine	Family physicians Additional personnel included: -Other physician -consultant -nurse -emergency room physician -Radiologist -Manufacturer of drug or equipment -Physician assistant -Other hospital personnel -Resident or intern -Technician	Not specified	Not specified	Most prevalent medical misadventures - Errors in diagnosis - None noted - Improper performance - Failure to supervise or monitor case - Medication errors - Failure or delay in referral or consultation - Failure to perform - Failure to recognise a complication of treatment - Failure to instruct or communicate with patient - Delay in performance Most prevalent associated medical issues: - Equipment malfunction - Problem with records - Problem with history or examination - Communications between providers - X-ray error - Improper conduct by physician	Review of claims/complaints database	Impact: - 8,797 claims resulted in payment to plaintiff. - Total indemnity paid for family physicians was $1.4 billion Harm: Severity of injury assigned to one of 9 categories as established by the national association of insurance commissioners severity index - Emotional injury only - Insignificant injury - Minor temporary injury - Major temporary injury - Minor permanent injury - Significant permanent injury - Major permanent injury - Grave injury - Death	18

					- Premature discharge - Lack of adequate facilities - Comorbid conditions - Unnecessary treatment Associated legal issues: - Informed consent - Abandonment - Failure to conform with rules, regulations - Breach of confidentiality - Assault and battery - False imprisonment			
Gaal et al, 2011, Netherlands	Family practice	Family physicians	Patient Family member Healthcare inspector Not retrieved	Not specified	Wrong diagnosis Insufficient medical care Wrong treatment Too late referral Incorrect statement or declaration Violation of privacy Not showing up or showing up too late at a house visit Provision of insufficient information Impolite behaviour Inappropriate patient contact Billing for treatment Other reasons Impossible to identify type of complaints for 19 cases	Review of claims/complaints database	Impact: - 134 cases (53.6%) were suspended - 18 cases (7.2%) were declared not applicable - 9 cases (3.6%) were withdrawn - 1 case (0.4%) was not further pursued by the plaintiff - In 88 cases (35.2%), the family physician was disciplined - Of the 88 negligence verdicts, 69 resulted in a warning, 11 in a reprimand, and 2 in a temporary suspension from practice - In 6 cases no disciplinary measure was given. All inappropriate patient contacts (100%), violations of privacy	22

							(64.3%), and an incorrect statement of declaration (53.3%) resulted in disciplinary measures Harm: - No health consequences - Small harm - Medium harm - Severe harm - Patient death - Health consequences unknown - Psychological or emotional - Minor physical - Significant physical - Major physical - Death	
Gandhi et al, 2006, USA	Ambulatory care	Primary care physicians radiology General surgery Pathology Physician's assistant Registered nurse or nurse practitioner Trainee	Not specified	Not specified	Diagnostic errors. Missed/delayed diagnosis Initial delay by the patient in seeking care Failure to obtain adequate medical history or physical examination Failure to order appropriate diagnostic or laboratory tests Adequate diagnostic or laboratory tests ordered but not performed Diagnostic or laboratory tests performed incorrectly Incorrect interpretation of diagnostic or laboratory tests Responsible provider did not receive diagnostic or laboratory tests results Diagnostic or laboratory tests were not transmitted to patient	Review of claims/complaints database	Harm: National Association of Insurance Commissioners 9 point severity scale. - Psychological or emotional - Minor physical - Significant physical - Major physical - Death	21

					Inappropriate or inadequate follow-up plan Failure to refer Failure of a requested referral to occur Failure of the referred-to clinician to convey relevant results to the referring clinician Patient nonadherence to the follow-up plan			
Harris, 1995, USA	Primary care	Primary care physicians	Patients	Not specified	Pap smear complaints Quality complaints - Issues of patient service - Technical quality of care - Patient access to care	Audit of medical records	Not specified	24
Hart & Weingarten, 1986, Israel	General practice	General practitioners	Not specified	Not specified	Received by local area director - Quality of the medicine - Doctor not investigating symptoms as much as the patient wanted - Refusal to see the patient - Professional style - Could not talk to own doctor about problems related to sex - Doctors attitude and demeanour - Sort of general practitioner he was (family or child/adult) - Clerk transferred them to a new doctor without asking Received by Regional director - Negligence - Refused house calls - Psychogeriatric mismanagement - Certification appeals	Description of experience of handling complaints	Impact: - Management was modified in 44 cases, usually after consultation with the doctor, except in a few special cases involving medical certification. - In 45 cases the problem was solved by referral to an agent which the doctor had not considered. (i.e., patients referred to specialists as a solution to complaints). - In 65 cases, the outcome was a change of doctor for the patient. - 68 complaints were dismissed completely.	8

					- Professional misconduct (One concerning alleged assault, and two concerning breaches of misconduct)		Of the complaints received by the regional director: - 3 were investigated by a Ministry of Health committee of inquiry, and in one case the doctor was reprimanded. - In three cases legal proceedings were instituted resulting in a fine for the doctor in one case, and a settlement out of court in another. - Four complaints were heard by the regional complaints committee, seven were received by the ombudsman, and two were given publicity in the national press.	
Lim et al, 1998, Singapore	Family health service	Doctors, nurses, registration clerks, to pharmacy staff.	Relatives Patients Friends Others	Not specified	Attitude/conduct - Rude/impolite/discourteous - Uncaring - Other conduct problems - Insensitive - Irresponsible - Arrogant/hostile Professional skills - Inadequate examination - Poor professional skills/incompetent - Inadequate explanation - Dispensing error - Poor professional conduct/attitude/style	Review of claims/complaints database	Impact: - It was found that 43% of complaint cases lodged were justifiable, 38% not justifiable, and 19% inconclusive. - In 47 of the complaint cases, it was difficult to conclude on their justification.	17

					- Wrong diagnosis - Unnecessary medical examination - Drug allergy missed Unmet patient expectations/requests Waiting time Communication - Unnecessary comments - Inadequate explanation - Other communication problems Registration - Registration problems - Medical records problems - Queue problems - Physical environment - Others - Other drug related problems - Social/racial discrimination - Inefficient phone answering system - Too young doctor - Inexperienced doctor - Move from place to place			
Mack et al, 2017, USA	Ambulatory care at a large academic cancer centre	Administration Finance Physician Nurse/nurse practitioner Psychosocial provider (e.g., social worker,	Patients themselves Spouse or partners Other family members Friend Referring provider on	Not specified	(Classified using HCAT) Management - Including service issues - Delays - Finance and billing - Access and admission Clinical care - Overall quality of care	Review of claims/complaints database	Impact: - Clarify normal process to patient - Apologise - Improve existing process - Transfer care to other provider or facility - Provide small service (gift card, parking)	27

		psychiatrist, psychologist) Pharmacy Medical services (e.g., lab, imaging) Non-medical services (e.g. food, retail) Infrastructure (e.g., parking, security Research Information technology Other	behalf of patient Social worker on behalf of patient Parent		- The patient journey - Treatment, and examinations - Skills and conduct of staff - Errors in diagnosis - Other safety incidents Relationships - Communication breakdown - Patient-staff dialogue - Incorrect information - Humaneness and caring - Patient rights		- Reschedule appointment - Supplement usual care process for patient - Adjust bill - Provide meeting with social worker - No action documented Harm: - 64% of complaints defined by the taxonomy as low severity - The remainder were rated as moderate or high severity	
Nettleton & Harding, 1994, UK	Family health	GPs	patient themselves, relatives, friends, warden of sheltered housing.	Not specified	Inadequate clinical treatment - Inappropriate prescribing - No action or treatment given when required - Misdiagnosis - No medical examination/investigation carried out - Inappropriate treatment - Persists with prescribing - Unsuccessful treatment - Unsatisfactory treatment - Contradictory diagnosis Practitioner not responding or co-operating - Failure to co-operate with services or equipment	Analysis of all informal complaints made to a Family Health Service Authority	Impact: - Letters sent from the FHSA to the complainant included: a sympathetic apology; an explanation to the effect that the FHSA is only empowered to investigate complaints that allege that a practitioner has failed to meet an obligation of service. It is pointed out that the matter complained about does not constitute a breach of contract; thanks the complainant for drawing attention to	15

					- Refused to put on list or struck off list - Refusal to visit - Refusal to refer - Refuses to sign certificate - Stops repeat prescription - Lack of information provided with diagnosis - Told to register with another GP - Refusal to prescribe - Forced to register with practice for a visit as temporary resident - Not taken seriously - Lack of ongoing care and support Personal attributes of the health professional - Manner - Poor spoken English - Will inform other GPs about patient - Disclosure about personal information Organisation of practice and staff - Difficulty making appointments - Manner of receptionists - No GP ever available - GPs administrative incompetence - Lack of surgery facilities - Administration of repeat prescriptions - Surgery cancelling appointments		the matter; sometimes advise complainants to take further action. - If breach of contract, administrator would consult a more senior officer. Most were not and in these cases a standard letter could be sent. Of the 112 letters received in 1990, there were 5 formal investigations.	

					- Surgery not equipped to carry out treatment Financial issues - Budget - Charging for a letter - Advised to go private - Charges Mistakes made by practitioner - Mistake on prescription - Mistake when dispensing - Dispensing out of date drugs - Inadequate disposal of drugs			
Owen, 1991, UK	General practice	General practitioners	Not specified	26% of letters said that the complainant's purpose in bringing the complaint was to prevent the same thing happening to other people.	Failure to visit Delay in visiting Failure to diagnose Error in prescription Failure to arrange emergency admission Delay in diagnosis Failure to examine Failure to refer for investigation or opinion Poor administration Delay in arranging emergency admission Delay in referral for investigation or opinion Miscellaneous Unsatisfactory attitude of general practitioner	Review of claims/complaints database	Impact: - Not determined Harm: - In 32% of letters the death of the subject patient was an important feature of the complaint	18
Phillips et al, 2004, USA	Primary care medicine	GPs, internists, paediatricians	Not specified	Not specified	Diagnosis error Wrong patient or body part Medication errors Improper performance Failure to instruct or communicate with patient	Review of claims/complaints dabase	Impact: - Half of closed claims were reported as having been reviewed for negligence	20

					Performed when not indicated or contraindicated Delay in performance Not performed Surgical foreign body left in patient after procedure Patient positioning problem Failure to supervise or monitor case Failure to recognise a complication of treatment Not or improperly performing resuscitation Failure/delay in admission to hospital Failure/delay in referral or consultation Improper supervision of resident or other staff personnel Failure to properly respond Surgical/procedural clearance contraindicated No medical misadventure Problems with records Consent issues Breach of contract Premature discharge from institution X-ray error Communication between providers Other		- Reviewed claims were more likely to result in an indemnity payment Harm: Severity classification of expert panel reviewed cases: - Low severity - moderate severity - high severity - death	
Pietroni & de Uray-Ura, 1994, UK	General practice (experimental primary health care centre)	Doctors, practice staff.	Patients	Not specified	Administrative - Repeat prescriptions - Telephone system - Receptionist - Administrative staff action or inaction - Appointment procedures Doctors or medical care or both - Delay or difficulty in getting prescriptions	Audit of an informal complaints procedure	Impact: - Letter of apology from health centre - Letter of explanation and clarification of health centre procedures - Resolved by meeting with general practitioner, patient, and patient's representative	15

					- Rudeness of doctor - Medical care - Appointments system - Telephone system - Waiting time - Doctor from deputising service Other NHS length of waiting lists for treatment.		- Explanation from hospital to which complaint was addressed - Not resolved.	
Quinn et al, 2017, USA	Outpatient general medicine	Outpatient general medicine physicians (internal medicine or family medicine)	Patient	Not specified	Diagnostic error (including failure or delay in ordering a diagnostic test, failure or delay in obtaining a consult or referral, failure to establish a differential diagnosis). Error in clinical judgement Error in communication	Review of claims/complaints database	Harm: National association of insurance commissioners injury Severity scale: - 0: Low, legal issue only, e.g., lost medical records, property damage, depositions - 1: Emotional only e.g. mental distress or suffering that is temporary (e.g., HIPAA violations, discrimination, false cancer diagnosis) - 2: Temporary insignificant (lacerations, contusions, minor scars, rashes, no delay in recovery) - 3: medium, Temporary minor (infections, fractures, missed fractures, recovery delayed)	20

							- 4: Temporary major (burns, surgical material left in patient, drug side effects, recovery delayed) - 5: Permanent minor (loss of fingers, loss or damage to organs, includes nondisabling injuries) - 6: High, Permanent significant (deafness, loss of limb, loss of eye, loss of one kidney or lung) - 7: Permanent major (paraplegia, blindness, loss of two limbs, brain damage) - 8: Permanent grave (quadriplegia, severe brain damage, lifelong care or fatal prognosis - 9: death Impact: - Cases Filed as suits (vs claim) n=282 (84%) - Cases resulting in indemnity payment n=163 (49%)	
Rodriguez et al, 2008, USA	Primary care & other specialties	Primary care physicians	Patients	Not specified	Classified as Access-related, or not.	Review of claims/complaints database		26

Wallace et al (2018), Ireland	Out of hours General practice	GPs triage Nurse administrative staff Multiple healthcare professionals Other	Parent/guardian Patient son/daughter Spouse/partner Other family member Healthcare professional Other	Not specified	Clinical - Diagnosis - Prescribing - Referral - Dissatisfaction with clinical examination - Unmet expectations regarding management - Misdiagnoses Relationship - Perceived rudeness - Abrupt manner - Inadequate explanation of diagnosis - Management plan - Dissatisfaction with the approach of the GP to the consultation Management - Dissatisfaction with payment for review consultations - Refund requests - Waiting time to see the GP - Suitability of infrastructure - Triage processes	Retrospective cohort study of patient complaints to an out of hours service provider	Impact: - 30 complaints against GPs were upheld and resulted in a formal apology to complainant. - Successfully defended to the satisfaction of both parties - Closed without agreement Harm: - No/minimal - Minor - Moderate - Major - Catastrophic	29