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Informing Policy with Evidence



Understanding the drivers of litigation in health services

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Key messages:

- The number and costs of NHS litigation claims are increasing over time.
- Parallel systems in the NHS monitor safety activity (drawing on data about adverse events) and complaints and claims data. These systems may be viewed as related, but are often managed separately. Consequently, data to track complaints and or adverse events through to claims is currently inadequate.
- Current PALS and complaints systems either fail to capture data or fail to share data that could systematically inform later claims. Where data is captured, little evidence of any correlation means there is sparse evidence to support the existence of a linear trajectory from adverse events and complaints into litigation and claims. From the limited data we have, it would appear that most adverse events do not result in claims, and litigation may arise with no previous history of complaint.
- There is no 'typical claimant'. Knowledge about the drivers for litigation, between and within groups or individuals, is sparse.
- The legal environment does appear to lead to changes in claimant behaviour. While 'no win, no fee' specialist medical claims solicitors may be reducing some speculative claims and directing claimants back to the NHS complaints process, there is a relatively low-risk environment for claimants, and non-specialist claimant solicitors may continue to support clients with weak litigation cases.
- There is a lack of good evidence on the effectiveness of interventions to reduce claims or costs. As such, further research is needed urgently, and any changes should be piloted alongside robust evaluation.
- Recent discussions reflect an increasingly widely held belief that tort litigation may not be the best way to deal with claims. A no-blame compensation system could potentially provide a clearer, quicker and more equitable option for claimants, and rapid information exchange to support harm reduction within the NHS.
- Where life-changing injuries/major harm occur, particularly during childbirth – the need to litigate is driven by the considerable future costs of care.

1. Background

When someone sustains an injury as part of NHS care, particularly a life changing injury that means they can no longer look after themselves or their family, they are likely to seek compensation. There are a number of differing systems in place across the UK. In Wales the NHS Redress Measure came into force in 2011, known as “Putting Things Right”. The new arrangements in Wales introduced one system which deals with both a complaint and a legal claim in cases where compensation is less than £25,000. Above this value, litigation still occurs as a fault-based system. Scotland and England both currently continue to operate a fault-based compensation scheme for medical injuries, and although Scotland considered moving to a no-fault compensation scheme, this has not progressed. There are a number of related compensation arrangements specific to Thalidomide, vaccines, Hepatitis C and HIV, Creutzfeld-Jakob Disease and specific interventions such as breast implants and hip replacements. These have often been put in place to avoid ongoing litigation or where public pressure raises the profile of issues where a legal claim is unlikely to succeed in proving negligence.

Current systems for seeking compensation are widely considered to be costly and protracted. Costs to the NHS are rising, but it is important to note that only a small proportion of people who have suffered any form of harm while in receipt of health care choose to pursue litigation. Evidence - mainly from outside the UK - suggests that many factors can sway people’s decisions about whether or not to take legal action. The degree of harm is only one of these factors.

In recent years, the cost of litigation has been the focus of several policy interventions in the UK and internationally. Most of these developments aim to minimise costs and improve the experience of patients, families and staff involved in the clinical negligence litigation process. The DH R&D Committee highlighted litigation as a research priority in March 2016. Given that the largest payments involve severe birth injuries, recent work has focused on a consultation for a Rapid Resolution and Redress Scheme for babies negligently harmed at birth. There is, however, a more general and growing interest in the costs of litigation, factors that may influence decisions to litigate and processes which may allow better tracking of the trajectory of litigation and resolution.

2. Purpose

This rapid response study aims to gather evidence about the factors that might affect the decision to litigate in England. We address the following questions:

- What are the trends in litigation over time?
- What factors have influenced trends?
- Is possible to identify a trajectory from complaints to litigation?
- Why do people litigate against the NHS?
- What purpose does litigation serve?
- What do people want from the process?
- Is it possible to identify key predictors of litigation?
- Are there people whose needs could be met outside litigation?
- What are the costs of litigation (psychological as well as financial)?
- Can claimants meaningfully be categorised?
- Can we learn about potentially effective interventions from international experience, or from other sectors?

3. Methods

We used a multi-method approach to address these questions, including:

1. A rapid scoping review of existing literature relating to patterns of complaints and litigation.
2. Re-analysis of a relevant existing qualitative dataset.
3. Primary interviews with stakeholders.

The project was approved by the ethical review committee of the Department of Health Sciences, University of York.

3.1 Scoping Review of literature

Scoping reviews are useful to examine the extent, range and nature of evidence in a particular topic area (Levac et al., 2010; Arksey & O’Malley, 2005) and refine subsequent research questions and studies (Davis et al. 2009). They collate and summarise of a range of evidence, including research and non-research material (Davis et al., 2009; Anderson et al., 2008). This approach is useful for this project given the short timescale, range of organisations and professions involved and the different types of evidence/literature available.

Previous NIHR funded research by one of the authors of this report (YB) examined evidence in the related area of open disclosure of adverse events in health care, often referred to in the NHS as ‘Being Open’ (Birks et al 2014). This research explored the way in which health care organisations and their staff communicate with patients and/or their carers following a patient safety incident. Guidance set out 10 key principles that underpinned the successful facilitation of this process including; providing a genuine and timely apology for what has happened, keeping patients and/or their carers informed about the progress made with the incident investigation, reassuring patients and/or carers that the incident is being taken seriously and ensuring that measures are taken to prevent the incident from happening again (NPSA 2005, 2009).

‘Being Open’ (Birks et al 2014) included examination of evidence in relation to open disclosure of adverse events in health care and litigation up to 2013. This review was broad and extensive and was, therefore, used as a starting point for further review. For this report, we updated searches from 2013 to 2018, conducting a search of a comprehensive on-line database – Web of Science – using the following search criteria, combined using Boolean logic operators:

- Terms related to litigation (e.g. litigation, claim, sue, legal action, lawsuit)
- Terms related to communication and attitude (e.g. communication, apology, transparency, honest)
- Terms related to clinical negligence (e.g. clinical negligence, error, malpractice, adverse event)

Limits applied: English language, humans, 2013 onwards.

Additionally, we hand-searched two key journals, Clinical Risk and BMJ Quality and Safety in Health Care from 2013 onwards. Finally, we sought key documents from relevant organisations including the Parliamentary and Health Service Ombudsman (PHSO), NHS Resolution, Care Quality Commission (CQC), National Audit Office (NAO), Medical Protection Society (MPS) and Department of Health and the Scottish Government.

Titles and abstracts were reviewed on the basis of topics rather than methods. We did not formally rate the quality of studies, or synthesise review findings in a meta-analysis. Instead we integrated the findings from published literature with qualitative findings by theme. Papers were classified into six categories: interventions to prevent litigation, factors influencing litigation, reasons for complaining formally or informally, trends in errors and adverse events, communication features that could prevent litigation, and drivers for litigation.

3.2 Re-analysis of existing qualitative dataset

We conducted secondary analyses of anonymised qualitative data collected from policy makers, health professionals and managers, representatives from professional and patient organisations and patients as part of a large study focussing on open disclosure (Birks et al., 2014). Table 1 summarises participant details and sampling notes.

Drivers for litigation were not the specific focus of the 'Being Open' study, but participants often discussed these in the course of their interviews. It is challenging to recruit to studies asking participants to discuss error and litigation, and this dataset allowed access to interviews with patients and practising clinicians, providing a useful basis for further interviews. All transcripts were re-read and the sections relating to litigation drivers were re-analysed thematically in line with the research questions outlined above. Qualitative data were managed using NVivo v10.

3.3 Primary interviews and data analysis

Further in-depth interviews with stakeholders took place between September and October 2017. All participants gave informed consent and all interviews were audio-recorded. Topics covered during the interviews were tailored appropriately to the job role of the participant, but were drawn from a pool of questions (listed in the topic guide, see Appendix 1). Discussion areas included the type of cases they dealt with, why they thought people litigate, typical case processes, and costs and trends of litigation. All interviews were transcribed and analysed thematically, in line with the research questions. Qualitative data were managed using NVivo v10.

We identified two initial key contacts, both risk managers that run local and national networks, and asked them to forward information about the study and a study invitation to their network colleagues/members. Members were asked to respond directly to the research team if they were willing to take part. Additionally, we were able to access legal colleagues through a collaborator on the earlier Being Open work. Other participants were identified through web-searching of organisational websites and via other participants.

We conducted interviews with 19 professionals working in different parts of the NHS complaints and litigation system (see Table 2).

Table 1: 'Being Open' study (2014) - participants, recruitment methods and sampling notes

Type of participant	Salient characteristics	Recruitment
Policy makers N = 7	Individuals who had been involved in health at policy level with an interest in open disclosure of adverse events with currently or in the recent past	Targeted letters to those involved in health policy with a role in patient safety or the Being Open guidance.
Representatives from professional organisations N = 16	Organisations which regulate or indemnify health professionals in the UK	Targeted letters to leaders of 23 professional organisations in the UK.
NHS Managers & Health professionals N = 54	NHS managers working in clinical or non-clinical roles. Included risk managers. Some managers have both clinical and non-clinical roles. 13 doctors; 22 nurses; 2 pharmacists 17 NHS managers	Targeted letters to senior managers in the five recruited Trusts and information disseminated through them to health professionals with our contact details. Efforts were made to recruit from a variety of ranks and professions but junior doctors were difficult to recruit.
Patients & patient organisations N = 5	Individuals either represented patient organisations or had experienced error or harm.	Information distributed to patient organisations and sent out to patients via the organisation with contact information. Targeted letters to leaders of patient organisations. Patients with positive experiences of disclosure were sought through healthcare Trusts but none were identified.
Other relevant individuals N= 2		Targeted letters to those identified as potentially suitable by other respondents.

Table 2: Professionals recruited to this study (2017)

Type of participant	Number approached	Number recruited	Response rate (%)
Patient representatives	7	4	57
Risk & complaints managers	7	6	86
PALS	4	2	50
DH Complaints Policy	2	2	100
Claimant solicitors	4	2	50
Health care litigation (non-solicitor)	2	2	100
Health care litigation (solicitor)	1	1	100
Other	1	0	0
Total	28	19	68

Most of the new interviews for this study were conducted via telephone but two people were interviewed together in-person and two others were interviewed individually but face-to-face.

4. Findings

The main topic of investigation for this project was litigation but, throughout this study, we have also drawn on some related areas through which there are perceived and anecdotal driving mechanisms for claims. Issues around complaints, adverse events/errors and communication have, therefore, also been examined. This reflects an underpinning assumption that complaints are linked to litigation, which we explored as the analyses progressed.

Using the search strategy summarised in the methods section, the updated search identified a number of new, potentially relevant documents in addition to the 2013 review. Where appropriate, these have been tabulated to provide detail, however a significant number of papers provided commentary rather than presenting data. A flow chart summarising the number of studies found, screened, and reviewed is available in Appendix 3.

In presenting the findings, we have synthesised the data from each phase of research under headings representing the questions posed in the research for clarity and to create a more integrated narrative.

4.1. What are the costs of litigation?

It is not clear what percentage of all people treated in the NHS pursue litigation. The National Audit Office's (2017) report showed that in the ten years between 2006/07 and 2016/18 the number of clinical negligence claims against the NHS in England (that were registered with NHS Resolution) doubled from 5,300 to 10,673, with a cost increase that quadrupled from £0.4bn to £1.6bn. Over the same time period (2006/7 to 2016/17), finished consultant episodes in English NHS hospitals increased by 33.4 per cent and finished admission episodes by 27.5 per cent (NHS Digital 2018), so the increases in clinical negligence claims and costs have been much faster than that of NHS activity. Increasing costs of claims are attributable to a rise in average claimant damages, an increased volume of claims being processed and increased legal costs (in 2016/17, for example, claimants' legal fees exceeded the damages awarded in 61% of successful claims). Much of the increase, both in number of claims and legal fees, have been in claims funded by Conditional Funding Arrangements (CFAs) or so called 'no-win, no-fee' cases, since their introduction in 1990, which were subject to changes in 2013. The most recent figures from NHS Resolution demonstrate that 10,673 new clinical claims were reported to NHS Resolution in 2017/18. Damages paid to claimants rose to a total of £1.63 billion in 2017/18 and rising legal costs make clinical negligence litigation an area of substantial spending. These costs are expected to continue to rise (NHS Resolution, 2018). When claimants receive lump sum compensation, the amount is adjusted according to the interest they can expect to receive by investing it. The recent reduction in the relevant discount rate, from 2.5% to minus 0.75%, contributes further to the rising cost of litigation (Ministry of Justice, 2017; Medical Protection Society, 2017).

"Defendant solicitors' cost - if you look at the stats they've remained relatively constant, with a slight upward trend but they're quite carefully controlled. The two areas that have increased significantly are the claimants' costs and that really is that big changes came around following the

reduction in the availability of public funding and Legal Aid support when there was a move more onto conditional fee agreements, and the instruction of a success fee, that had a significant impact, and the introduction of the need to have after the event insurance premiums as part of the claim to cover the CFA. Those costs they've gone up quite significantly over time, but the largest spend is obviously on the amount of damages that are paid and that's a function of an increased volume of claims over the period that we're talking about. Then in the last year or so, very significant inflationary pressures caused by the change in the discount rate, obviously the government's recently published that legislation with a view to looking at that again, but at the moment we're in a period where the cost of a claim involving significant future loss, recurring loss have increased very dramatically because of the discount rate change". (New data. Risk Manager)

In addition to the factual information available in reports a number of interviewees expressed their thoughts on the costs attributed to litigation.

"I haven't got the values here but values have gone up very considerably and particularly the average values for the most severe cases have, I mean when I first started at the NHSLA about fourteen and a half years ago, the average cost of a brain-damaged baby case was around three million pounds, now we're seeing some coming in at over ten million pounds, so the cost of obstetric claims in particular has risen very sharply but there are increasingly complex care packages and increasing life expectancies as well which factor into that." (Being Open Data. Solicitor)

"My solicitor's estimate is that it cost the NHS over a hundred thousand pounds in unnecessary costs to prolong the case and all the specialists for both sides had been booked to attend court, when the case was admitted, when they settled or when they agreed liability the case was cancelled three days before, all those consultants, all those specialists all charged their fees because they had already booked the date that's how it works, all the solicitors charge their fees, it's just pouring NHS money down the drain. " (Being Open Data. Patient)

"Changes in the value really, the cost of the process and the cost to the NHS of clinical negligence that has changed very significantly over the time that I've been involved in this work". (New data. Solicitor)

There are clearly other costs, beyond the financial costs of litigation, and a broad and well-documented research base addresses the effect of error, harm and subsequent investigation and litigation on staff. This large volume of literature on the so-called 'second victims' of errors was outside the scope of this review, but the effects of involvement in error and subsequent litigation broadly encompass emotional, cognitive, and behavioural problems for staff involved. In coping with these challenges, staff may employ coping strategies that subsequently impact on their patients, colleagues, and themselves ranging from sickness absence, or practising defensively through to leaving their profession altogether.

"I think that's a very important factor, people's careers, not necessarily their careers but their morale and their self-confidence and mental state is often very badly affected by involvement in an incident and counselling is quite often inadequate." (Being Open Data. Clinician)

"Then similarly for staff members, if they've been involved in a claim - no, not so much claims - but inquests, certainly and claims - inquests sometimes turn to claims and they're invested. It's nurses who treated this patient for two months or whatever else. They get really emotionally involved with it and they're really upset". (New data. Para-legal)

The negative effects of litigation and investigations were highlighted, but we also talked to individuals who believed that some specialities were more resilient in the face of adverse events, serious incidents and investigations, with surgeons highlighted as more resilient than obstetricians, midwives and physicians. Those working in risk management were keen to state that they tried to keep the workload minimised for staff, but they acknowledged the difficulties staff face.

"If it then progresses they'll (consultants) look at the particulars of the claim. So we're adding on another couple of hours, it depends. They might maybe need to go to a conference with experts and barristers. That's a half a day or a day and then a trial could be anytime. So it's a not insignificant amount of time for them, plus I'm sure the actual time of getting on with it and writing a report is nothing compared the time for some of them of worrying about it. I'm not aware of any consultants - I'm aware of other staff that have stopped practising in their field in large part due to being involved in a claim. Whether it was the straw that broke the camel's back..." (New data. Legal services manager)

The cost to families in pursuing litigation can also have serious effects on quality of life and health, as well as financial implications. The Being Open interviews were a sample who in most cases had been involved in protracted legal cases of a catastrophic nature, rather than less perhaps lower graded levels of harm. For this group, clear psychological trauma was evident.

"I had to re-mortgage my home and it was difficult." (Family member, Being Open Data)

"I haven't worked since he died, and it's taken over my life. I mean, it's 22 years, I mean I don't know how much it's worth and it isn't about money, that, to me, is water under the bridge. But, we've deserved compensation for what they did, we wouldn't have taken them to court. If they'd been honest, the worst case scenario for them is £5,000 we wouldn't have wanted the money, it wasn't about £5,000." (Being Open Data. Family member)

"The emotional cost of it is very difficult, you know, having to go over the things - they don't want to go over those, they certainly don't want to go over them in a solicitor's office, they certainly don't want to go over them with somebody who is perceived as unsympathetic - although I have to say, I have never heard of a solicitor who does this work who is not helpful and who is unsympathetic. Generally, clients tell me that solicitors are really good. It's the healthcare professionals that are the problem" (New data. Patient Advocate)

There was uniform recognition of the costs to the NHS, organisations and individuals in relation to claims. Literature and interviews both highlight the personal costs of litigation for both professionals and patients. Given the reduction in social care provision it is also possible that the costs of individual claims may rise to take into account the need to budget for future care costs.

4.2. What do we know about trends and factors that may influence litigation?

4.2.1. Litigation

Overall there appear to be four main trends highlighted in relation to litigation from the interview data. These are supported to some extent by current existing data trends.

- Basic change in people's behaviour
- Changes in expectations of and relationships with patients
- Easier access to litigation/solicitors
- Move by new solicitors into the market

A number of interviews were with individuals who had been part of the NHS for long periods of time, some over 20 years. They noted a shift from a paternalistic model of health care to a very different model that promotes equality of relationships and transparency, in principle if not always in practice. Alongside this, however, they noted a difference in the attitudes of different generations in relation to making claims. There was a sense that older people were less challenging in relation to care generally, and less likely to litigate. This is supported by current data trends. There were also concerns about increasing expectations created by debate around patient-centred services and the resources available to meet expectations.

“This is the best we can do, we don't have the resources to do what we want to do, so actually we have to mend and make do a bit. People, if they don't understand that, have an expectation that their care will be equivalent to some privately-funded healthcare”. (New data. Complaints manager)

“People almost used to be embarrassed, certainly older people. When they used to tell me things they'd say, 'You know, I don't want anyone to know I'm doing a claim because I don't want anyone to think bad of me for suing the NHS because they're brilliant.' Then now it's kind of nobody thinks like that anymore. Now it's just, 'Yes, make a claim.' They're open about it whereas before they were very like - it was almost taboo to make a claim against the NHS and it was frowned upon”. (New data. Paralegal)

The experiences of interview participants working in the areas of complaint, risk and legal management or in bodies dealing with registration and governance of health care professionals all suggested that patients and their families now had greater access to information around litigation. Many believed that both patients and staff had a greater awareness of complaints and litigation in relation to health care services and professional codes. Alongside this greater awareness, participants argued that patients now had free access to litigation because of increases in conditional fee arrangements (no-win, no-fee) that would likely affect litigation levels. Representatives of professional governance bodies (NMC and GMC) noted an increase in the number of complainants bypassing Trust and NHS complaints processes and instead, making direct referral to them.

“I think unfortunately it's the way of the world, I think everybody thinks you can sue everybody. I think from our experience people think we live in America and everybody can just sue for anything and they don't realise. We do try to explain it's quite a difficult process, you have to have significant grounds to be able to sue, but then we would advise them to speak to a solicitor. Some people that say they want to take legal action, it's just silly, they're not going to get anywhere. I don't know, I just think it's the way of the world, I think people just want to throw, 'I'm going to sue you' around”. (New data. Patient advocate)

“People have changed, people have become more aware of their rights and there's much more freely available legislation. Freely available litigation as well. which didn't happen, you very rarely saw a solicitor, certainly when I started taking on claims just did not occur and things did go wrong,

"we know they went wrong and they still do but now there's, you know there's all the ambulance chasers where there's a claim there's a blame" (Being Open Data. Risk manager)

"The last study that was done said only a small percentage of people want compensation, but we do find it is quite a high percentage that come in and say.' Well I want some money because you have done this" (New data. Claims Investigator)

"So there's quite a number of new solicitors firms acting for patients who have entered the market who - I think most people would regard them as not being the most expert and I genuinely don't think that that helps patients because you're never sure how well they're being advised in terms of the prospects of success of a claim, what they can expect from it, what they can expect in terms of levels of damages, that kind of thing. So it certainly concerns me, not because it's wasting my time particularly but more that it's wasting public funds and it's creating or perpetuating false expectations for the patient" (New data. Risk manager)

While anxiety around the new Duty of Candour legislation was apparent at its introduction, the predicted rise in claims was suggested not to have materialised.

"I suppose the only thing that surprised me slightly is that I did wonder whether or not the new duty of candour regulations would have an impact on our claims, and they don't seem to have affected it either way, so we've started to track whether or not they were duty of candour matters, and it just doesn't seem to have affected our numbers or types of claims". (New data. Claims manager)

Fenn et al. (2016) analysed three national UK datasets to assess whether methods of funding clinical negligence claims affected the number and types of claims, the types of claimants and the outcomes of claims. Their analysis showed that socio-economic status of claimants had changed between 2001 and 2013. In the earlier period, people on middle incomes were less likely to make a claim, but by 2013, these groups represented the highest frequency of claimants after adverse events. Newly opened claims doubled between 2001 and 2013, a change that correlated with changes to the legal funding system and the emergence of conditional funding arrangements (CFAs) and with an increase in annual spend on claim payments by NHS LA. CFA funded cases are, in general, lower value, shorter and incur lower costs than Legal Aid cases. It is important to note, however, that only complex cases related to birth injuries (which are likely to take longer so that the full impact of the injury can be determined and to result in high compensation payouts), are eligible for legal aid, so this finding is unsurprising.

Mead (2014), reporting NHS Litigation Authority data, showed that there was an increase of 66% in surgical litigation claims between 2008 and 2013; the highest percentage of claims by volume related to orthopaedics (49%). The data also revealed that cardiac and neurological surgery claims tended to lead to larger payments - 4% and 11% of costs compared with 2% and 4% of incidence, respectively.

Studies specifically related to litigation are summarised in Table 3. These papers reported findings from reviews of national or regional insurance, court or litigation data. The studies focused on particular medical specialties and reported the main reasons for litigation, and/or costs of litigation to health care organisations, and/or the time it takes from incident to litigation. Only two of the papers made recommendations about how to minimise litigation in the future.

Table 3: Reports of studies related to litigation rates

Reference	Type of paper	Location	Specialty	Key findings
Breen et al., 2017, Pediatric Radiology	Study - review of relevant cases (71) in Drs' Insurance database	US/Canada	Paediatric Radiology	<p>Radiology was the primary service responsible for 71/1,472 (4.8%) paediatric cases. The most common allegation was failure to diagnose. These result in high payouts particularly for missed diagnoses of congenital and developmental anomalies. Conclusion - improved training on diagnostication is required.</p> <p>Limitations: Database only included around 30% of malpractice claims in the US - but it does provide a cross-section of different systems of healthcare provision in US; Authors did not look at secondary responsibility within claims.</p>
Nagashima et al., 2017, Neuro Med Chir (Tokyo)	Study - Review of national court records re medical malpractice	Japan	Neurosurgery	<p>The number of malpractice litigation claims has risen - up to 800 per year and surgery accounts for a sixth of these. There were 446 healthcare-related decisions retrieved (for years 2001 and 2005). 41 of these related to neurosurgery. Principles citations for litigations - diagnosis (4), clinical judgement (4), technical skills (26), clinical management (4).</p> <p>Court decisions about medical malpractice have reduced since 2007 but since 2009 up to 2015, they are increasing again.</p> <p>Limitations: The court system only discloses a proportion of cases. Thus, this sample was drawn from only those cases that were released.</p>
Fenn et al., 2016, Nuffield Foundation	Study – reviewed three national datasets to compare impact of different ways of funding claims	UK	All specialties	<p>Analysed national data from three datasets (The Compensation Recovery Unit; the Ipsos Mori survey and the NHS LA datasets).</p> <p>These showed that there had been a change in socio-economic status of people claiming between 2001 and 2013 with more middle-income people claiming latterly; legal costs were higher as a proportion in conditional fee arrangements (CFA) funded claims but overall of lower value; newly opened claims doubled between 2009 and 2013 which coincides with the predominant route for funding claims being CFAs.</p>

Chen et al., 2015, The Knee	Study - analysis of NHS LA data re: litigation for knee/hip replacements	England	Orthopaedic	<p>Costs and trends in litigation claims in the NHS between 2005 and 2010. Overall costs for knee surgery litigation = £10.4m. Identified 515 cases - 298 of which were total knee replacements. Most of the successful claims were related to retained drains, incorrect type/wrong sized prosthesis.</p> <p>Conclusion – To reduce litigation, it is essential to identify ways to minimise technical errors such as incorrect types or size of prosthesis and prosthesis malalignment and strategies to minimise the risk of retained drains.</p>
Colaco et al., 2015, Journal of Emergency Medicine	Study - Review of jury verdict reports in malpractice	US	Urology	<p>Testicular torsion cases 2000 to 2013. 52 cases identified - 51% found in favour of medic, 49% received an indemnity payment (13% of these settlement). ER doctors are the most likely to be sued for this and ER doctors are more likely than urologists to end up making a malpractice payment.</p> <p>Conclusion - ER doctors should seek advice from urologists when there is a suspected case of testicular torsion.</p> <p>Limitations: Only includes those cases that got to trial not those that settled prior to hearing.</p>
Thyoka, 2015, European Journal of Pediatric surgery	Study - NHS LA data reviewed	England	Paediatric surgery	<p>2004-2012 closed cases reviewed. 112 claims related to paediatric surgery - 73 (56%) closed and settled (17 of these were fatalities); 20 (18%) closed without payment; and 19 (17%) remain open. Main reasons for litigation: post-op complications (28%); delayed treatment (22%); diagnosis (19%). Median time between case lodged from occurrence - 2 years (range 0-13 years) and 75% of cases were settled within 3 years.</p> <p>Conclusion - 2/3rds of claimants receive a payment. Median payment - £13537 (range £600-£500,000); Median cost borne by NHS - £31, 443 (£600 - £730,202)</p>

Paik et al., 2014, Aesthetic Surgery Journal	Study - review of US litigation database in relation to breast surgery.	US (New Jersey)	Plastic surgery	<p>292 cases (verdicts or settlements) between 1985 and 2012. Breast-related surgery accounts for 37% of claims against plastic surgeons and there are increasing numbers of breast-related malpractice claims. Disfigurement most common cause of litigation. Negligence was cited in 88.7% of cases. Augmentation accounts for - 39.4% of claims; reduction accounts for - 37.7 % of claims).</p> <p>Cases that cited lack of informed consent as part of the reason for the litigation were 35% less likely to receive a favourable outcome for claimant.</p>
McWilliams et al., 2013, Bone and Joint Journal	Study - review of NHS LA data on Total knee & total hip replacements	England	Orthopaedic	<p>Review of NHSLA (NHS Resolution) data between 1995 and 2010. 1527 cases of litigation related to total hip replacement (THR) and total knee replacement (TKR). Main cause of litigation from THR was neuro deficit and from TKR was infection.</p> <p>Reasons for litigation mainly unchanged over time but rates differed - infection dropped by 6%, alleged negligence rose by 11%, technical errors increased by 4-5% (these were included in a 3rd of all relevant claims), claims in the miscellaneous category fell by 8%. Authors suggest that there has been a vast increase in the number of operations performed but no corresponding increase in litigation.</p> <p>CONCLUSIONS: Rates of litigation reduced - proportion of litigation has fallen per operation</p> <p>There is no evidence that orthopaedic surgeons are subject to a more litigious culture.</p> <p>Limitations: No data available before 2002 in England</p>
Seabury et al., 2013, Health Affairs	Study - review of an insurance database assessing length of cases	US	All	<p>Reviewed malpractice claims data for all 40916 physicians on closed cases between 1995 and 2005 for 'time from claim filed' to 'claim closed' and 'time from incident to 'claim filed'. Mean time from incident to resolution = 43 months (Mean time to resolution - 20.3 months; Mean time from incident to file claim - 22.8 months)</p> <p>More severe harm = longer to resolution/close</p> <p>No payments = 6 months or more; 81% closed in 1yr or more; 27% 3 years or more.</p>

While narratives did emerge around broad groups of people who claimed, as well as the types of claims made, a variety of views were expressed. There was a sense of more activity around low-value claims, and perhaps a lower rate of success in terms of these being awarded. Some respondents also acknowledged a greater sense of activity around issues relating to falls and pressure ulcers. There was a sense that some of the patient safety work had highlighted these areas to patients and the public and changed expectations around these areas.

"I certainly think that the levels of injuries, the levels of harm, which people seem to be pursuing in litigation is a lot less than it used to be, so people are pursuing legal cases, going to solicitors for things that - and I wouldn't insult them to say are trivial, but certainly would not be the things that would have been litigated five/ten years ago. So temporary, transient problems, short-term issues, that either they, the patient, wouldn't have gone to lawyers about or indeed lawyers would have followed with them". (New data. Risk manager)

"For the cohort that are more often than not seeking financial redress is usually a lower correlation with actually being awarded that compensation, I would say, because they tend to be the less - the more disingenuous claims". (New data. Legal services manager)

In between the clear cases of harm, and the more speculative cases, there seems to be the majority of the work. This appears to be related to cases where harm and liability are less clear and thus may be the area where, potentially, most change is possible.

"If it's a case where the Trust feels that the care was acceptable, supported by independent experts, then the claimant may come around to that view and the claim may be discontinued and fall away, or at the other extreme it may be a claim where there's an acceptance by the Trust after investigation that the care was negligent and that the patient sadly came to harm as a result, and there'll be admissions of liability and compensation will be worked out. The bit in the middle is the greyer area where there remains a difference of view between the claimant and the defendant and the experts, that's a difference about how the care should be characterised, whether it was acceptable or not, and in those cases either compromise will be reached on a risk basis, or ultimately if that's not possible then a few cases will go to court and a judge will be asked to make a decision based on the different evidence." (New data. Solicitor)

4.2.2. Adverse Events and Errors

The context of treatment within the NHS is changing. There is a long-standing trend of increasing demand for treatment, which since 2010 has exceeded funding increases (Kings Fund, 2016). Over ten years, the number of patients treated in hospitals in the NHS in England has increased by 4.6 million (27%), while the number of outpatient attendances has increased by 19% (Bojke et al 2017). Patients also have more complex needs, with increasing numbers having long-term conditions and multiple morbidities (Kings Fund, 2013). Risky births, which account for some of the most costly litigation claims, are also changing in number and nature, with more births to older women and more multiple births over time, although other risk factors, such as smoking during pregnancy, are falling slightly (ONS, 2016).

A number of papers discussed trends in adverse events over time. While these may seem somewhat removed from direct relevance to litigation, there is an assumed link between underpinning events or

errors and a trajectory to complaints and claims (Breen et al, 2017; Chen et al, 2015; Colaco et al, 2015; McWilliams et al, 2013; Mello et al, 2014c; Nagashima et al, 2017; Paik et al, 2014; Saber-Tehrani et al, 2013; Seabury et al; 2013; Thyoka, 2015). In most of the published literature no explicit links to future claims were made, and these papers often focused on institutional learning from a safety perspective. Such papers do, however, highlight the challenges faced in making comparisons between contexts and studies. A retrospective review of patient records in Ireland (Rafter et al., 2017) indicated a 12% prevalence of adverse events in admissions and an incidence of 10.3% per 100 admissions. They found that this was a larger proportion of adverse events per hospital admission than is indicated in the Irish datasets.

It is important to bear in mind the different methodological approaches identified in the literature looking at patterns of adverse events. Ethnographic and national reporting information (Jha et al., 2013), retrospective patient record review (Baines et al., 2013; 2015; Rafter et al., 2017) and a prospective cohort study (Calder et al. 2013) are quite different approaches and make it very challenging to identify patterns in the adverse events which may underpin claims. This reflects, in part, varying definitions of harm, adverse events, and temporal factors. Comparing events over time, for example, might be problematic, as medical advances might affect whether an error was 'avoidable'. Similarly, international comparisons can be problematic: for example, comparing hospital adverse events between countries with a strong hospital-based healthcare system and those with a strong community-based healthcare system might lead to spurious conclusions. Possible challenges of comparison might also arise if relying on national datasets of adverse events. Rafter et al. (2017) suggests that national databases of adverse events might underestimate events. Thus, although these data provide some insight into event trends in different countries it is important to note that national approaches are influenced by their local data and recording systems.

Singh et al. (2014; 2017) estimated that 1 in 20 adult patients in the US are subject to diagnostic errors. Diagnostic errors accounted for over a quarter of claims and for 35% of malpractice payments. They were also the leading cause of claims related to death and disability in the US (Saber-Tehrani et al., 2013). Given the burden that diagnostic errors place on the medico-legal system, strategies that might reduce errors are key to minimising litigation. These papers refer to a requirement for improved diagnostic training, but no research was identified evaluating such recommendations, or training or other strategies to minimise diagnostic errors.

4.2.3. Complaints

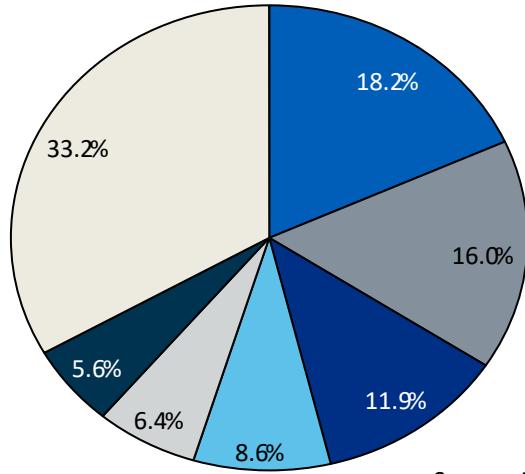
Data on national levels of written complaints (NHS Digital) and on costs of clinical negligence (National Audit Office) are both reported annually. These are easily accessible and the data are not reproduced extensively here, but are summarised.

NHS Digital (2017) reported that there were 208,415 written complaints annually to the NHS. This figure rose 4.9% from the previous year but was similar to the 2014-15 statistics. Figures for 2016/17 showed that complaints were made mostly by the patient themselves and the majority of complaints came from those aged 25-55. When analysed by service area, the largest proportion was attributed to

inpatient services (31.3%) and a third of all hospital complaints were related to clinical treatment, 41% of which were attributed to the medical profession.

Figure 1: Complaints by Subject Area, England

Clinical Treatment (including Errors)	19,368
Communications	16,981
Staff	
Attitude/Behaviour/Values	12,688
Appointment Availability/Length	9,113
Appointment (Obtaining inc 084 numbers)	6,786
Prescription Issues	5,995
Subject <5%	35,295
Total	106,226



Source: NHS Digital

(084 numbers are non-geographical telephone numbers used to provide extra functionality and improve access for patients. Historically such numbers were used and cost the caller 7 pence per minute. Since 2010 the DH has issued guidance stating such numbers must not cost callers more than an equivalent call from a geographical landline).

During 2016-17 a total of 195,778 complaints were resolved. The remainder are carried forward into the next reporting period. Of these resolved complaints 71,460 (36.5%) were fully upheld, 42,690 (21.8%) were partially upheld and 81,628 (41.7%) were not upheld. If a complaint is received which relates to one specific issue, and substantive evidence is found to support the complaint, then the complaint should be recorded as upheld. Where a complaint is made about several issues, if one or more of these, (but not all), are upheld then the complaint should be recorded as partially upheld. Where there is no evidence to support any aspects of a complaint made, the complaint should be recorded as not upheld.

While there is good data on numbers of complaints available, interview participants were keen to raise awareness of the limitations in relation to what such data can communicate. Comparisons of complaints data between hospitals and over time may not always convey clear messages, although interviewees made some suggestions of how to use data better, for example encouraging Trusts to provide information on responses to complaints, and to explore and potentially report complaints within the same area, which might be more informative than the total number.

"There is a major problem with using quantitative data they tell you virtually nothing. You can compare year on year, or quarter on quarter but the content of those data...If you'd asked me that question ten years ago it would be virtually none of my claims would have been through complaints process. People either claimed or they made a complaint. I'm probably getting my timescale slightly wrong, because it's maybe not quite as much as ten years, but then the rules on the funding for claimants changed and so then my understanding is that quite often claimant's solicitors will say to patients, 'Go and make a complaint. It's free. Come back to me when you've got your complaint'

response'. Then that gives them a starter for ten as to whether or not there's anything." (New data. Legal services manager)

Harris and Byhoff's (2016) US study focussed on rates of medical board disciplinary action rates and therefore did not provide information about the number of complaints or claims. Bismark et al.'s (2013) study reviewed an Australian dataset of all formal complaints made to the Ombudsman against medical professionals. This indicated that 3% of the workforce accounted for 49% of the claims and identified four factors associated with increased risk of complaint – doctor's specialty, sex, number of previous complaints and time since last complaint. Spittal et al. (2014) developed a model from the Bismark et al paper to predict medico-legal risk based on these factors. While the focus of this work is on complaints, targeting interventions, support and training at these 'at-risk' groups may reduce the number of complaints, and possibly, claims brought if the trajectory from complaints to claims can be supported (Birkeland, 2016).

A number of studies had examined trends in complaints and the underpinning causes of complaints and are presented in Table 4.

None of the papers discussed their findings in relation to levels of formal complaints or litigation, and in some cases, the idea of formal and informal complaints was raised as contentious. For some analysts and legal colleagues a complaint stood regardless of how it was categorised. The issue appeared to relate to where it was dealt with and whether it had to be recorded, and some interviewees expressed the view that separating formal and informal complaints is unhelpful and inappropriate.

In the Being Open data, a trend in increased complaints directly to professional bodies was highlighted.

"There's been a significant increase in direct referral from the public in relation to nursing and midwifery in this year. And I've been a matron here for eight years now and this year, I think up to this last 12 months, I knew of one family that had referred somebody to the NMC." (Being Open Data. Professional's organisation)

"This year, I think I've seen about six. And we've known about them, they've not complained to us, they've complained directly to the NMC." (Being Open Data. Complaints manager)

The data also identified that engaging with the volume of complaints may be problematic for some staff. This account conflicts with later data from other participants who stress the value of talking to people to minimise misunderstandings and prevent escalation.

"Yes, the majority of them we don't even speak to the families unless there are specific questions that are directed at an individual. If they ask any questions about my management of their relative or whatever then I do try and bring them in, especially when it's a patient who's died and explained things to them but the majority of times I just kind of accept it's going to work its way through the motions. And often, if it's seen to be an unjustified complaint then to be honest I'll just put that down to somebody else's problem. I've got enough to be doing with ... if we've genuinely done something wrong, or it's clearly somebody who's just grieving and wants to know what's happened to their relative, who died in our care, then I will make the effort, get them in but we get too many complaints to do that for everybody, we haven't got enough time." (Being Open Data. Clinician)

Table 4: Reports of 'other' studies related to relevant trends

Reference	Type of paper	Location	Specialty	Key findings
Kemp et al., 2016, BMJ Qual Saf	Study - telephone administered patient experience survey of 8929 patients.	Canada - Alberta	All	<p>Paper reports on the informal complaints made during the telephone administered survey of patients in 2013-2014. Of the 8929 patients surveyed, 1870 patient made 'open-ended' complaints. Most common complaints were related to nursing care (491); medication management (219); and food (193). Complainants were more likely to be younger, born in Canada with no documented co-morbidities. Patients whose length of stay was less than 3 days, were male, had a lower educational level, had experienced an urgent admission and were a lower resource intensive cases were less likely to make an informal complaint as part of the survey.</p> <p>The authors did not look at formal complaints or the link between complaint and overall experience score.</p>
Panesar et al., 2015, BMJ Qual Saf	Study - systematic review	-	Primary Care	<p>Paper reports on papers reporting patient safety incidents. Literature searched from 1980 until 2014 and included 9 systematic reviews and 100 primary studies.</p> <p>Studies reported between <1 and 24 patient safety incidents per 100 primary care consultations. Population based records indicated that the median number of patient safety incidents is 2-3 per 100 consultations. The paper concludes that patient safety issues in primary care are a relatively frequent occurrence but most do not lead to significant harm. 4% of incidents were linked to severe harm and these were linked to diagnosis and prescribing issues.</p>
Ausserhofer et al., 2014, BMJ Qual Saf	Study - secondary analysis of European nurse survey data (RN4CAST)	International - 12 EU countries	Nursing	<p>Analysis of nurse survey data on informal complaints from 30 hospitals per country (Belgium, England, Finland, Germany, Greece, Ireland, Netherlands, Norway, Poland, Spain, Sweden, Switzerland) about nursing care left undone.</p> <p>The main tasks left undone were psychological care, care planning and documentation and the main reasons cited were nurses having to carry out non-nursing tasks and higher patient to staff ratios (i.e. limited time to fulfil nursing tasks). The paper did not report on the impact of leaving tasks undone.</p> <p>It was not possible to draw out the impact of nursing tasks left undone or whether harm arose from the factors that led to the informal complaints (e.g. nursing care, medication management and food).</p>

4.2.4. Communication

The literature and qualitative findings reflect a widely held belief in the link between better communication and reduced litigation. While better communication and early disclosure may improve outcomes in terms of relationships and resolution, no robust evidence was evident regarding the impact of better communication in isolation (i.e. without financial resolution) on litigation activity or amounts in empirical studies (Obermair et al, 2013; Ernesater et al, 2014). The relatively recent Duty of Candour legislation was not always felt to have made an impact beyond process motivations.

"I don't believe that duty of candour has fundamentally altered that. I don't deal with it myself but the impression I get is it's, or can be very easily, a bit of a tick-box exercise in terms of whether the duty of candour is formally triggered according to the very specific rules about levels of harm. Therefore, whether you follow a particular process in terms of early acknowledgement, written letter, and that very prescriptive process, as opposed to what would just ordinarily happen in terms of I'm sorry this has happened, we're going to look into it, and we'll let you know the results. That can still happen and that did happen before, without duty of candour, that here is now a very specific and prescriptive process to follow if it is triggered, but I'm not sure that that's fundamentally changed the situation. I think it's more over a number of years we have become more honest, and I'm going back five, ten plus years. We have generally become more honest and probably more thorough." (New data. Risk manager)

Some raised the issue of meeting patient and family expectations by delivering investigation outputs in a timely and accessible manner, particularly in complex cases.

"I still think we struggle, and again it's easy for me to say because I don't carry out those investigations, I think we still struggle with meeting people's expectations around how quickly we can do that because sometimes - a lot, a number, of cases, they involve more than one speciality, they involve more than one clinical team, and actually investigating that, getting the right people to look into it and coming up with a comprehensive and relatively easy-to-read Root Cause Analysis investigation, incident investigation, report, takes time. Sometimes into months rather weeks, and it's around getting the availability of the clinical staff, to sit down and go through the notes and plot the details carefully and then come up with the conclusions and learning the lessons and things like that. So I think we still struggle with delivering that in a timescale that's expected and satisfies the patient." (New data. Risk manager)

A number of authors suggest that poorly conducted disclosure can increase claims. Seven of the papers about communication focused on open disclosure (Ushie et al., 2013; Berlin et al., 2014; Birks, 2014; Johnson et al., 2014; Youngson, 2014; Birks et al., 2015; Mira et al. 2017). These included research about whether health professionals are prepared to disclose error (Berlin et al, 2014), why practitioners do or do not disclose error (Birks, 2014; Birks et al., 2015) and recommendations for improving communication when an error has occurred (Johnson et al., 2014; Youngson, 2014; Mira et al., 2017). Although most of these papers made reference to levels of litigation related to open disclosure, none provided additional evidence to indicate that disclosure could impact upon litigation levels. Ushie et al.'s study aimed to assess likelihood of litigation post voluntary disclosure of an error. The survey of 269 in-patients in Nigeria (who had not experienced harm) suggested voluntary disclosure would reduce intention to litigate. However, the prospective and hypothetical nature of the

study limits its applicability in real world scenarios, and the health care system context is very different to that of the English NHS.

Three papers focused on communication-based approaches to deal with complaints/claims with the aim of reducing litigation (Lown et al, 2013; Durand et al, 2015; Moore and Mello, 2017). Lown et al. (2013) described a shared decision-making intervention, which seemed to improve practitioner reflection and learning, but the authors did not report evidence on impact on litigation. While the qualitative data we collected had a number of accounts from clinicians suggesting that their experience and practice of better, shared decision-making led to fewer complaints and litigation, a systematic review of international evidence (Durand et al., 2015) concluded that there was insufficient evidence to determine whether these processes affect levels of medical malpractice claims. Qualitative work in New Zealand by Moore and Mello (2017) explored the factors that influence the success of reconciliation processes following a medical error within the 'no fault' system. While they suggest reconciliation was successful in avoiding legal action they highlight the need for processes to be tailored to the claimant and the situation and as with other studies the role of communication independent of other parts of any wider reconciliation processes is difficult to isolate.

"So what I am trying to explain to you is the different scenarios in which one breaks bad news, most people are very sensible and receptive but you get the occasional situation where they are not and then you've got to still learn to cope with it. And basically remain professional and dignified and respectful. You've got to remember that a patient, any service like us, the patient must be key and we are really only there all the time to serve and so it is very important that we should not be arrogant or dismissive, or judgemental in any of these scenarios". (Being Open Data. Clinician)

"For instance, and this is a bit of a personal bugbear of mine, we investigate a case and it's not about the person who's writing in, it's their daughter or grandmother, and we call the person either we're talking about or writing to the wrong name. Or we refer to a period of care in the wrong year, or we refer to a date and we get the date wrong. Now, if I poured my heart into a letter of complaint, and I'm probably not typical of people who complain and I probably wouldn't think twice - I would think - or I would think twice about writing a very formal letter of complaint, but if I got those things back in a letter from a large organisation, that would annoy me intensely. When it's so personal about your partner, your child, your grandmother, and you haven't even got their name right, I can understand people being aggrieved by that and I have seen that happen." (New data. Risk manager)

Strong evidence supporting a direct association between improved communication and reductions in litigation was limited, however some of the qualitative reports provided powerful observations around how communication may have an important role in moderating the sometimes challenging relationships that occur when the views of professionals and families are not well-aligned (Roing et al, 2014; Bismark et al, 2013b; Paterson, 2013). Some highlighted careless communication and the use of 'non-apologies' where the emotion of the patient or family is acknowledged but no responsibility taken. Other respondents raised a tendency for more recently qualified staff to pass any indication of discontent onto a complaints process rather than trying to resolve issues early and in a less formal context.

“Basically clients describe it as a half-hearted apology, so it's saying they're sorry that you felt like that but not saying they're sorry we made you feel like that, they're saying we're sorry you felt like that. Do you understand?” (New data. Patient Advocate)

“I don't know whether it's the new intake of nursing students, or medical students or whatever, I really don't know because I haven't managed to speak to large groups of them, but whether they feel that that is the way that families' concerns are dealt with and that they can't do them, or are not able to do them, I really don't know. That's something that I'm going to hopefully help with. In my day, makes me sound really old, but in my day, we didn't have PALS, you did manage it like that. The vast majority of clinical care was customer care, they expect you do be good at your job but actually the things that matter the most to them is that human factor to it.” (New data. PALS and Complaints manager)

The families' context was also highlighted as important. Often families are confused and angry and interviewees acknowledged the challenges in being faced with these situations. These families were often bereaved and searching for answers, and staff described them as distressing and sometime frightening scenarios.

“I'm very concerned by the fact that these people are left to manage these very difficult emotions, massive anger - and I'm talking about real - I described it to somebody, my supervisor, as 'room-filling anger' - it fills the whole room for some of these people, and that's understandable.” (New data. Patient Advocate)

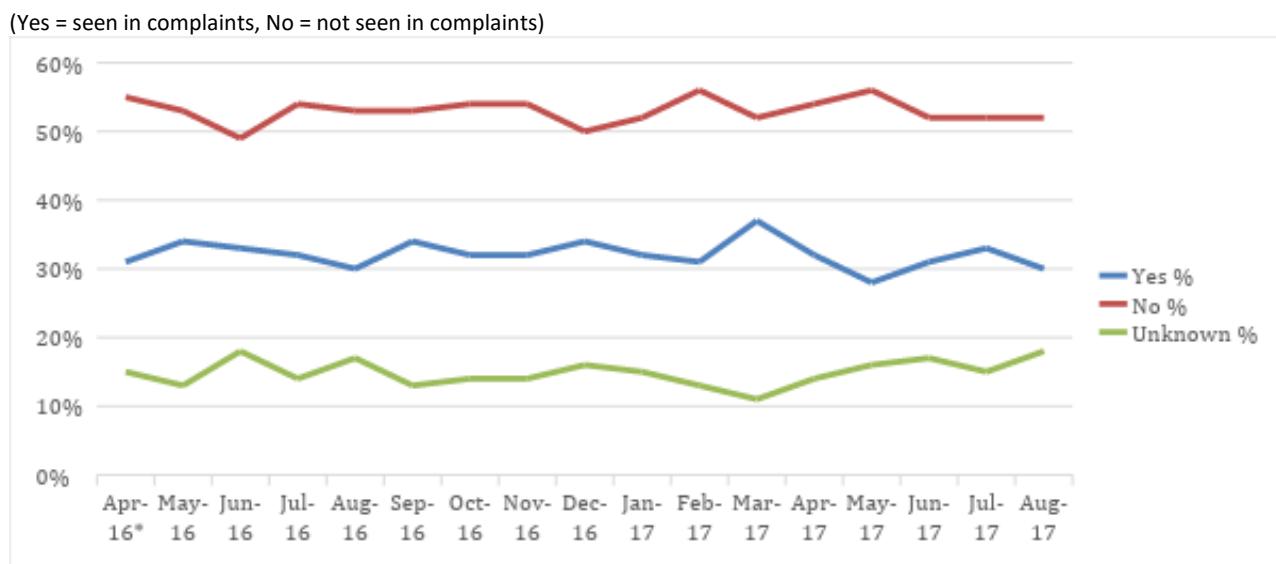
4.3. Is it possible to identify a trajectory from complaints to litigation?

The trajectory from complaints to litigation is not straightforward. While dissatisfied patients may be directed to PALS, it is also possible that they may seek the advice of an independent body such as the Patients' Association. These organisations encourage patients to use the NHS system. There was a sense in interviews that merely tracking the route to litigation may not be as useful as some believe, and that early and more granular information may be of greater help.

Data from NHS Resolution's Case Management System (Figure 2) shows that over 50% of claims do not appear through a complaints route, and a further 11-18% having no information on their trajectory.

The Case Management System data demonstrates that tracking of the trajectory of incidents into claims is necessarily limited since the majority of claims may miss the complaints route to claims. A recent pilot study by NHS Resolution in obstetrics and orthopaedics (shared confidentially for the purposes of this report) introduced a scheme in four English NHS Trusts. The aim of the pilot was to explore whether this trajectory (incidents, complaints and claims) could identify earlier triggers for potential harm with the potential to improve patient safety, and reduce frustration claims generated by poor communication, lack of candour and inadequate apology.

Figure 2. Number and percentage of clinical negligence claims received between April 2016-Aug 2017 by month of receipt and complaint investigation type (as at date claim reported to NHS Resolution).



All trusts in the pilot acknowledged that this work in identifying contributing factors across incidents, complaints and claims endorsed their view that early candour and involving patients fully with the investigative process could have improved their complaints and claims handling by alerting internal teams to potential incidents at an earlier stage. The most common contributory factor for claims found across all four trusts was lack of effective communication between internal teams and across NHS networks.

Our interviews also highlighted that many potential claimants had not engaged with the NHS complaints system before approaching legal representatives.

"One of the first questions that I used to have to ask was - when we - it was in the new case, New Client team, was, 'Have you gone through the complaints route?' Probably ten per cent." (New data. Paralegal)

We also found evidence of some Trusts making more effort to join the services of PALS and complaints together to provide a more client focused service, although not all supported this configuration. The role of PALS was not uniformly supported and variability regardless of any joint process was highlighted as an important factor in making any process of raising and resolving complaints or concerns effective.

"She and I do a combined paper every year. But of course I wouldn't necessarily - it could end with me. If they don't end with me and I don't know they're wanting money at that point, but then subsequently they take their response to a solicitor and then it goes in to her, I wouldn't necessarily always know that. That's about we don't use the same database. I don't really want a report from her every month, you know, that all these have converted because actually they're now in her process and not in mine and I'm too busy. It would be interesting, but I haven't got the capacity to be able to track that." (New data. Complaints manager)

“I just think it's absolutely key because you need to know. If somebody's been through the complaints process first, then that might tell you something about your organisational response to the complaint. If your conversion rate from complaints to claims is high, then actually is there something in our complaints responses or complaints procedures that actually we need to be reviewing and doing a bit better? Actually, could we have prevented it from progressing to a litigious matter.” (New data. Legal affairs manager)

“Where I was before, because I was dealing with the legal stuff and the coroner's stuff, it was great. If you picked up a PALS case or formal complaints, that was also to do with a claim, for example, or there was inquest going on, then there was that better oversight. You could pull those processes together and people not working in silos I think. Obviously, it is different here because they've got their own legal department and their own risk department.” (New data. PALS and Complaints manager)

Participants also talked about the uncertainty of knowing whether someone was going to pursue a claim or not. They described situations where it appeared that someone might have accepted a situation when going through the complaints process only to pursue a claim when they had had time to think about it away from the immediacy of the situation and from the clinical environment.

“Initially, she was just relieved she hadn't got cancer and everything had healed up nicely and she was happy. She just said to me, “oh well, I'd have probably wanted that tissue removed anyway,” and she specifically didn't want any further follow up. So, I did say there'd be an investigation, but then she didn't really want any follow up on it. Now, interestingly and not surprisingly, a couple of months later, she's made a formal complaint, cause she's now had time to reflect on what's happened and she wants to know why the mistake has happened.” (Being Open Data. Complaints manager)

Several factors were highlighted which participants felt might mean a complaint would result in litigation. These included cases where patients and families had unrealistic expectations about the intervention or the outcome of it, where they refused to communicate about the incident/outcome and where they remained angry during the investigation/complaint process, especially where the patient/family suggested that the investigation constituted a ‘cover up’.

“I would say that 75% of people are, but there are the 25% that will not accept anything. Sometimes you wonder whether there's a bit of an ulterior motive or they've already got the mindset before they come that nothing we will say, 'cause it's all a big cover up. In their minds they know exactly why this has happened and they will go on to make a claim...” (New data. Legal services manager)

Observing these ‘risk factors’, therefore, might give an indication of whether a case might go forward to litigation and might be able to be used as predictors of litigation as indicated in the pilot work by NHS Resolution reported earlier. Although participants suggested that they might ‘know’ that a particular family would litigate, they also acknowledged that the diversity and uniqueness of cases made it difficult to identify predictive factors.

“I suppose you are very much on guard that if a family is particularly upset and definitely want, quite often they just want something that, not sure what that something is, the family just wants something and quite often just saying to them well actually this is not going to happen again

because we've put this procedure in place isn't enough. So you can sort of judge whether they are going to take it further or whether they are going to be happy with your explanation. And it may well come across to the family if you are behaving defensively because you feel that they are behaving offensively and that maybe makes things worse" (Being Open Data. Complaints manager)

4.3.1. Why do people litigate and what purpose does it serve?

Those working in claims management and complaints suggested a variety of reasons why people might litigate including:

- a desire to be compensated for harm
- to prevent harm happening to others
- to achieve explanations about poor outcomes
- to hold the service to account
- emotional response to loss

"Could their needs and wants be met outside of litigation? Many, yes, but still at least a third are looking for financial recompense." (New data. Claims manager)

"People get conflicting information or they get ambiguous information from doctors and nurses and they end up not trusting anybody, and so even when somebody is being absolutely honest and explaining things in great transparency, they still don't believe them because they're the third or the fourth or the fifth person that's told them something and it's been different each time. That sounds incredibly fundamental and almost naïve, but I think it's possibly one of the biggest influences because if somebody explains to you how something's happened, what they're going to do to put it right, what they're going to do to stop it happening again, I'm sure that a lot of people just accept that and move on, whereas some people, if they don't get that, they will be forced down the litigation route. I still don't think that that will give them the answers they want, but it's just it's the route by default because none of the other routes have given them the information or the answers they want." (New data. Risk manager)

"For some people it is, yes - there's no doubt about that; but - and there's a 'but' behind that - I think my sense of that is that these people are not just after the money because that's the only thing that they want; they are seeking that money either to be able to manage their lives following very devastating consequences, or as a way of - because their perception is that the money is the only thing that matters to organisations, and so what they want to do is to be able to use that as a lever for an apology." (New data. Advocate)

"How the patients are treated will have a big impact in terms of how people speak to them, how people explain things to them, how people try to put right what's happened, and logically that must be the case. I can see, if only evidenced by the medical records and the letters that go backwards and forwards, if people have raised a slight concern and then either that's not treated seriously or it doesn't look like it's being treated seriously, it becomes a bigger concern. They write a letter of complaint, we take months to answer that complaint, don't answer it very well, that, again, I can see would encourage them to pursue a claim because they just haven't got the answers any other way. I'm not sure that pursuing litigation is the right way to get a response or to get that information, but if they've exhausted or at least tried other routes and not been successful, then I can certainly understand that that could well be a motivator." (New data. Risk manager)

"We get flat out requests for compensation. We do get people saying I want an apology, I want an explanation. We get people wanting staff disciplined, struck off, sacked." (New data. Claims Investigator)

"What we've found is people don't necessarily want heads to roll or they don't - they don't want it, something to happen to anybody else and they want learnings. Quite often people say, 'I just don't want it to happen to anyone else.' (New data. Independent Patient Advice Helpline)

"Just saying things the wrong way can send hares running really and people think that the poor outcome they've got is entirely ... some people are looking for blame. They're looking for a reason particularly when they're traumatised or someone's died. Their initial reaction is to try and blame someone or something and they'll pick out things and they might not be able to listen very well because of their heightened state of emotion." (Being Open Data. NHS Manager)

There was little additional information about the purpose litigation served or other things claimants want from the process. The professionals interviewed did discuss some challenges they encountered through risk management and the complaints processes in relation to the tension between unanticipated or poor outcomes as opposed to harm. One of the main challenges was managing uncertainty within the context of health-care decision-making. In the same way that professionals argued that higher societal expectations influenced whether people would attempt to litigate, they also felt that expectations affected risk management decisions.

"Our license for managing uncertainty is reducing all the time, public perceptions, demands of society, whatever... have changed and will no longer tolerate people making judgements that don't turn out to be correct,perfectly happy for you to make judgements which turn out to be correct but if it turns out to be incorrect well then it is probably going to be your fault". (Being Open Data. Clinician)

"I think people come at it from a slightly different angle, particularly when you are breaking bad news or saying to families look this young child is going to die. You know usually it is not from our mistake, it's usually from a head injury or from a horrible stroke or something, something natural. But you've tried your best and you've now got to the point where you can't do any more. But sometimes those relatives can be very unrealistic". (Being Open Data. Clinician)

Severity of harm and the resulting effects on people's lives was the single most important factor in determining whether post-harm legal action occurred in the Being Open data.¹ Literature also suggested that some individuals report using litigation to get answers, often linked to the discovery or sense that an error occurred in their care that was not disclosed at the time.²

"Had they told us the truth when R died, had they possibly shed a tear, had they shown remorse, some of them were parents themselves, yeah, then, I'm not saying I'd shake their hand and forgive them, but human beings make mistakes, as do doctors. And there was nothing I could have done to change the situation, R's always gonna be dead, unfortunately, and I knew that. But when they started to lie and cover up, it was something I had more difficulty with". (Being Open Data. Family member)

¹ Birks et al 2014; pages 24 and 28

² Birks et al 2014; pages 23-24

In a report for the Scottish Parliament in 2012³ findings suggested that patients' grievances, complaints and even claims were not necessarily related to a specific medical event but rather to communication problems, staff attitudes and poor general care. This is also illustrated in data collected by NHS Digital on complaints, and the pilot study referred to earlier in this report by NHS Resolution, which supports an important potential role for improved internal communication in addressing progress to litigation. Participants felt that sometimes staff attitudes and behaviour in the clinical setting and through the complaints process could drive litigation. This was especially the case when patients felt they had been lied to and that clinical and/or complaints staff were not acknowledging their pain, suffering and/or distress:

"They're about the communication, they're about the saying sorry, they're about saying sorry in a way that is genuine, about making some kind of restitution - and it's not necessarily money; about allowing people to work with them to make sure it doesn't happen again, because people need to feel that something purposeful has come out of this event, that it's not just been pointless." (New data. Patient advocate)

Some participants suggested that patients and their families sometimes had unrealistic expectations of care and outcomes of interventions and that this could lead to litigation.

"The number of complaints isn't just coming about you know nursing care or they've had a bad experience, it is about... I have seen some literature about this and it is about their expectations. They demand more, and I think sometimes those demands are quite unrealistic. The complaints are now turning into claims and although I would and I am sure my colleagues hold their hands up to say "I am sorry...", you have said sorry, "we didn't quite meet those standards" and then 2 or 3 months later you are getting in complaints from a solicitor to say they are going for trauma and distress. It is a real, real thing that is coming through'. (Being Open Data. NHS Manager)

The way that complaints were handled could also determine whether patients and their families sought a legal case. Sometimes, patients wanted to raise awareness of an issue within and across organisations, trigger change in practice in the clinical and the complaints contexts, and gain further information:

"Normally, a serious incident, we'll give them a timeline of between eight and ten weeks of providing a full report and an offer of a meeting to be able to go through that with the family. Quite often, the family might be waiting six months, 12 months, and you can imagine how distressing that is. They feel that they've got no other route to go down other than litigation because it feels like the organisation isn't learning, hasn't taken it seriously, has made lots of promises that they've then gone onto break, so people, yes, will then go down a litigation route as well." (New data. Legal services manager)

"I've really recently been to a mediation in one of our civil claims, and it was really interesting speaking to the claimant and her husband. We weren't able to resolve the claim at mediation, but we had some really positive feedback. The claimant's husband actually said to me, 'It's the first time we've seen somebody from the trust who's apologised to us', and I think they went through quite a lengthy complaints process. They had two formal complaint responses. They were offered a meeting, and I don't know whether or not they took that up, and they subsequently went to the ombudsman. I'm not sure in that case what the outcome of the ombudsman was, but, given that I

³ <http://www.gov.scot/Topics/Health/Policy/No-Fault-Compensation>

wasn't part of that investigation, and I'm not clinical, I was surprised at the power of my apology. Now, whether or not that would have stopped that family from pursuing that matter, I don't know, but they felt very strongly that the information contained within the complaint response was incorrect, and, obviously, subsequently, since we've had the independent expert review, we have had to concede liability, so I guess some of the content of that complaint response wasn't accurate." (New data. Claims manager)

Ipsos MORI's (2016) qualitative study, including interviews with parents/families who had experience brain injury during birth, showed that parents often only understand the full implications of birth injury when the child misses developmental milestones, and this can mean that there is a delay in seeking compensation. Whilst bereaved parents did suggest that getting answers and ensuring the NHS learned from what happened motivated them to sue the NHS, the main driver for parents/families facing life with a child with complex disabilities and an uncertain future may be to secure the financial stability and continuity of care for the child. These findings align with evidence provided earlier in this review, which indicate that the main driver of litigation for adults is severity of harm.

"The kind of claims I am involved with at this stage in my career tend to be claims arising from obstetric negligence, so the injured claimant who is a child who has been brain damaged during delivery usually, and so the difference that a successful claim can make to that family is remarkable because in a successful claim then there will be funding for a professional private care regime for the lifetime of the child and have all the necessary therapies, adapted accommodation etc., so if you contrast that with a family who has got the same child with a disability but who can't prove that disability is caused by negligence then they will obviously be managing on what is available to them from the state. And the difference will be vast. So I think in that context the motivation will be the real difference a claim would make to their life and the life of the child that they are bringing up" (Being Open Data. Solicitor)

While a number of policies around addressing the needs of families and complaints handling have been informed by the Making Amends Consultation paper of 2003, the validity of this underpinning data was questioned by some. Within this consultation MORI were commissioned to determine what people wanted from a system of redress. Of the nearly 5% who had been affected by medical injury, the main responses they reported wanted from the NHS were: an apology or explanation (34%), an enquiry into the causes (23%), support in coping with the consequences (17%), financial compensation (11%) and disciplinary action (6%). Aside from the small scale of the respondent pool, it is important to note that the respondents were only able to give one response, which is likely to bias results as individuals may be concerned about appearing preoccupied with financial reconciliation. Follow-up work by Gray et al (2017) repeated this survey in 2013 and, while the proportion of people reporting an adverse event fell significantly to 2.5%, the proportion who had pursued a legal claim was almost unchanged at 10.5% (10.7% in 2001) and preferences for responses also remained stable.

The likely motivations for claims may often be multi-faceted and complex and grounded in the context of the care and the family.

"It's frustration that the matter hasn't been dealt with appropriately by the doctor, hospital or trust. It's often a case of I don't want this happening again to somebody else, so things have to be

changed and they need to be highlighted. It can also be if that person has suffered problems as a result of not being able to work or what have you and of course some people claim because they know they're entitled to compensation if somebody else has negligently hurt them." (New data. Claimant solicitor)

Individual respondents did however highlight some cases where they felt unable to understand the individual patient or family's pursuit of a claim.

"I'm thinking of one case at the moment and I honestly can't think of why this man is pursuing. He's gone through the complaints process, he's now pursuing a claim. Normally you can put your finger on it, they might have financial difficulties, they are expecting some kind of compensation or apology. Even if they've gone through the Ombudsman after the complaints process and that might not have gone anywhere, it is another route of escalating it and if they keep going round someone will say 'yes you're right, and they are wrong." (New data. Claims Investigator)

4.4. Are there international examples, or examples from other sectors, of effective interventions from which we can learn?

The Being Open research found limited evidence from the US and some European countries suggesting that disclosure and compensation schemes (disclosure with offer) can deter litigation.⁴ Further analysis suggested it was difficult to disentangle how much the disclosure or the compensation individually contributed to the finding that spend on litigation was reduced. However, such schemes appeared to contribute to maintaining trust within the relationship between claimant and organisation as well as making the process easier for the claimant and a reduction in litigation costs were evident.⁵

Mello et al (2014) reported data on paid litigation claims in the USA. These indicated a sharp reduction in paid claims since 2007, with median payments reduced by 1.1% per year since then. The authors examined differences in legal processes to explain these reductions and argued that there is no evidence that the reduction is a result of changes to legal systems such as mandatory pre-suit notifications laws, apology laws, state-facilitated dispute resolution laws, safe-harbours, or judge-directed negotiations. There was some evidence to suggest that, depending on environment and culture, administrative compensations schemes (such as those evident in New Zealand and Sweden) can reduce costs because claims are resolved more quickly compared to tort-based systems. There was no evidence, however, that these systems affect the number of claims. Mello et al. also reported that there was some evidence that communication and compensation schemes (e.g. the Michigan and Kentucky models) can reduce malpractice claims, but they point out these were tested in very specific clinical environments (e.g. self-insured hospitals, localities where tort reforms are strong, and systems that employ most of their physicians directly).

At present in England, compensation for medical injuries can be sought through tort litigation, with payouts made through out-of-court settlements or through the courts. No fault compensation schemes (NFCSSs) may provide an alternative, and some consider, a fairer method to redress claims resulting from medical injury.

⁴ Birks et al 2014; pages 28-29; 38-39

⁵ Birks et al 2014; page 36

The Dental Complaints Service was established in 2006 by the General Dental Council.⁶ It works by attempting to resolve personal injury problems in the context of a service-level problem. This may involve remedial treatment, a refund, an apology or an explanation. Payments can be made for pain and suffering, but these are reported as rare, and most patients who use the service seem to remain within the same dental practice and in some cases with the same dentist (Macleod and Hodges 2017). The website is clear and easy to navigate and the level of service explicit.

A range of injury compensation schemes have been instituted in other countries for injuries which do not require claimants to establish fault, described briefly in Table 5.

Dickson et al.'s (2016) review of 'no-fault' compensation schemes described different approaches but did not present definitive evidence on their comparative effectiveness. It did however illustrate the challenges to gaining in-depth understanding of different schemes and the context in which they exist. In the 44 papers they examined relating to medical and non-medical injury they identified the context and mechanisms involved in no-fault compensation and tort reform that may lead to intended outcomes. While largely untested so far, early findings are summarised in Table 6.

A recent text by Macleod and Hodges (2017) reviewed the intricacies of over 40 international personal injury compensation schemes including those addressing patient harm. This extends the work of Dickson (2016). They propose that one of the key issues in relation to many schemes is the confusion around the meaning of 'no-fault' compensation terminology. They suggest this has been used incorrectly in relation to the NHS Redress Act 2006 where compensation is based on an existing liability in tort. While the term has been used to describe various schemes including wider trigger, non-tort, or non-court schemes, the authors argue that there has never actually been a truly no-fault compensation scheme, as an element of limiting eligibility in some way retains an element of 'fault'. They suggest the term 'no-blame' provides a clearer option. Macleod and Hodges argue for a move away from tort as the trigger for liability to a system which provides a less combative approach. This approach has driven changes in Nordic countries where the the need for honest and open relationships to underpin the system, without blame, are stressed. While this is likely to be an important factor it is unclear how this might translate to England where current evidence suggests that fear of litigation may only be one of a set of complex drivers that challenge openness in relation to error and adverse events.

Across health systems and other personal injury contexts, there is a general move to create no-blame schemes. This suggests broad support for the idea that tort litigation may not be the best way to deal with claims. Broader points suggest such a system is clearer and quicker for claimants, reduces the costs associated with administration and litigation and is more equitable. Macleod and Hodges (2017) suggest that while the UK has attempted to introduce an open, no-blame, complaint reporting system they have maintained a fault and litigation based system for injury compensation which is likely to compromise open reporting. They also caution that while the two no-blame systems in the UK (clinical injuries in Scotland and the scheme for birth related brain injuries in England) may produce benefits there are examples where such schemes are not working as predicted and detailed design remains critical.

⁶ <https://dcs.gdc-uk.org/>

Table 5: Overview of compensation schemes for medical injury

Key components	United States (since 1990)	France (since 2002)	Nordic countries (since 1975)	New Zealand (since 2005)
Eligibility criteria for compensation	No-fault: Proof that the neurological birth injury occurred as a result of the birth process	No-fault standard: Serious and unpredictable injuries, without relation to their previous state of health and foreseeable evolution Fault standard: Failure to act in accordance with current scientific data or 'gross or intentional conduct'	Avoidability standard: Injuries could have been avoided if the care provided had been of optimal quality Unavoidable injuries (Denmark): Rare and severe consequences of treatment that exceeds what a patient should 'reasonably be expected to endure'	Unexpected treatment injury – for those in employment
Continued access to courts	No	Yes	No – they only become available if appealing a decision	No
How schemes are funded	Annual financial contribution made by participating doctors and hospitals	No-fault: ONIAM (A tax-based, government-funded administrative body) Fault: Providers/insurers	Patient insurance schemes funded by a range of public and private health care providers	Government via tax revenue and employer financial premiums
Financial cap	Yes	No	Yes	Yes
Financial entitlements	Economic and non-economic damages	Economic and noneconomic damages	Economic and noneconomic damages	Economic damages

Dickson et al (2016)

The final section of Macleod and Hodges (2017) makes detailed suggestions for the parameters and outline for compensation schemes based on evidence from around the world and schemes from outside health care, but stresses the importance of national, local and organisational context. The important link between the speed at which information can be collated from no-blame schemes to further inform harm reduction is highlighted.

Table 6. Context – mechanism - outcome configurations (from Dickson 2016)

Outcomes	Context and mechanism potentially influencing outcomes
Justice 1: Access to courts	To make compensation schemes attractive to claimants, they must <i>offer payment and broader eligibility criteria</i> , to ensure schemes remain more appealing than the tort-based system.
Justice 2: Equality of access	NFCSSs that are <i>free to access</i> improve justice outcomes in that they are <i>accessible to all eligible parties</i> , unlike the tort system, which favours those who can afford legal representation.
Justice 3: Transparency of process	Transparency of process achieves justice through the <i>representation of the claimant</i> , and mechanisms that improve the <i>consistency of decision making through the use of medical experts</i> and the consideration of precedents.
Justice 4: Compensation decoupled from disciplinary procedures	Creating a separation between compensation procedures and disciplinary procedures enables improved access to justice and a more efficient compensation scheme, since physicians are more ready to hand over the relevant information.
Clinical practice 1: Defensive medicine	Tort reform and NFCSSs <i>reduce unnecessary tests and procedures</i> and <i>improve access to health care for patients considered 'riskier' by clinicians</i> , because doctors are less likely to practise positive and/or negative defensive medicine ⁷ to protect themselves from litigation.
Patient safety 1: Admitting to error	NFCSSs improve patient safety by enabling physicians to disclose iatrogenic injury through the removal of personal liability, applying the avoidability criterion and decoupling compensation from disciplinary procedures.
Patient safety 2: Learning from error	NFCSSs improve patient safety by enabling the pooling and sharing of information about medical errors and by reframing the compensation process as a patient safety strategy rather than a risk management strategy.
Health 1: Physical health	NFCSSs and tort reform improve the physical health of patients by <i>shortening the length of time to claim closure</i> and by <i>including a rehabilitative element in the award</i> .
Health 2: Mental health	NFCSSs and tort improve the mental health of patients by shortening the length of time to claim closure and by removing the adversarial element of the tort system

⁷ Positive defensive medicine: when clinicians attempt to protect themselves by being over-cautious in their practice. Negative defensive medicine: restricting or denying care or treatment to patients considered too 'risky' by clinicians.

4.5. Are there people whose needs could be met outside litigation?

In a context of rising litigation it is important to consider whether there are people who currently engage with a litigation who might be more satisfied with a system which allows their issues to be explored and settled outside of the current systems. This involves exploration of clear trajectories into complaints and onwards to litigation to identify points where intervention may be directed.

"You've got the trusts' legal costs, the NHSR costs, claimant lawyer's costs, emotional cost and the emotional impact not only on the injured person but also their family and friends. Everything needs to be geared towards what I call fast, fair resolution of the case. It keeps the trauma down to a minimum on the claimant's and their family and friend's behalf. It keeps the costs down. It keeps the aggro down. It keeps the bitterness down and we just need to get to a situation where cases are identified as negligence as soon as possible and if that happens the day after or the day and there's an apology by the doctor that's documented under the duty of candour and it can all be dealt with like that fine. But as soon as it gets into the lawyer's hands it needs to be dealt with as quickly and efficiently as possible as well with collaborating with the NHSR. The NHSR need to change their mindset so they're in a position where they are comfortable with collaboration, negotiation and boxing cases up as quickly as possible as well, which I think they very much are at the top, but there's a massive disconnect between that and what actually happens day-to-day on the ground." (New data. Claimant Solicitor)

"I would say it would be everybody in the NHS were living and breathing the duty of candour and being true to it and admitting to mistakes when they're made and dealing with them as I say in as fast and fair way as possible, because I think you'd have a lot more outcomes on behalf of the injured person. You'd reduce cost and I actually think at the end of the day everybody wins from a situation like that if lawyers' fees have to be pared back as a result of that, but a faster and fairer system where people should be recompensed for doing a good job then so be it." (New data. Claimant Solicitor)

"But we've got this thing that we've got the NHS Litigation Authority, for very good reasons, since the mid-90s, has been running this risk pool system. What it does is it almost pushes people into litigation. If you can just say, 'Oh, I'm really sorry, that's a mistake. Can we offer you this?' Which is more or less what the rest of the commercial sector do. I know they want your business to go back. They don't do it, whereas the NHS, you more or less unless you're absolutely loaded you've got to go to the NHS, but you get the point. It's just all these things that we seem not to be looking at. We've become obsessed with litigation and reducing costs of litigation instead of saying, 'Well, is there any way we can just cut litigation out in the vast majority of cases?'" (New data. Legal services manager)

"I think sometimes just listening. Sometimes it isn't necessarily a complaint in the first place, it's a rant or a bit of a moan. You just want someone to listen to you, and if they don't, or they don't seem interested, or you don't feel like you're being taken seriously, we often find that when it is a formal complaint it's never about one thing, it's almost always a series of things...and you end up with something that could have been a quick win, a quick conversation, and a ten point complaint." (New data. Claims Investigator)

The lack of any thorough tracking of data through from concerns and complaints through to claims and litigation itself has been highlighted by NHS Resolution in the pilot work shared with this team (page 26 of this report) as well as by DH colleagues and the House of Commons Committee of Public Accounts

(2017), who concluded that '*a lack of consistent data across the system means the NHS does not understand why people do (or do not) make claims, or the root causes of the negligence*'. This makes it challenging to determine, in any systematic way where points of intervention might be directed, and what the underpinning logic might be in developing such a model of intervention. Interview data suggests that while professionals closest to patients sometimes feel that there may be people who are determined to litigate, in a number of cases a more comprehensive acknowledgement of distress, timely and efficient processes, the space and skill to listen and address concerns may avoid a number of complaints and possibly claims.

"They've been happy withthat went wrong, this is what we're doing about it and I think because they've been spoken to and kept up to date, having gone home, at no point have they felt the need to put pen to paper or involve solicitors or anything." (Being Open Data. Clinician)

"Locally, for us here, it's a huge problem and our claims profile could probably be halved if actually we got it right at the complaint stage or investigation stage. If we invested the energy at that end of the event, our claims profile would reduce quite dramatically, and I'm sure that'd be true across the board really for a lot of people." (New data. Legal services manager)

"I've got one at the moment where, if somebody had taken the time to invite the family in, or they'd gone to see the family at home, and gone through the medical records with the family and talked about the surgical complications, and talked about what the nurses had done, and how the nurses had escalated their concerns, I'm almost certain that they wouldn't be making a claim against us, and they are, and they have done it out of frustration, because a year and nine months after their relative's death, they still feel like the questions that they had at the time haven't been answered." (New data. Claims manager)

"I've sat through so many inquests with aggrieved families really cross and they sit there and you can see the penny drop...this is years ago when we weren't as good as we are now at sharing things beforehand - where they say, 'Oh that's why they did that. Oh, I understand that now. Oh right, that's why that was'. By the end of that process they would be content if you like. So you think actually somebody in the middle you just think actually they maybe haven't had things explained properly to them, that sort of thing." (New data. Legal services manager)

Some felt the further conversations were removed from the clinical encounter, the more likely they are to become complaints or claims.

"For me, it's about developing that culture at the coalface, if you like. The staff will just say, 'I can't speak to you about it now,' or 'Let's let them make an arrangement to sit down and talk about this, I'll get the consultant to come and speak to you,' or, 'Let's get you to speak to the ward manager or the matron' or whatever, so they nip it in the bud and deal with it there and then. I think, that is invariably the better way to deal with it but it's not always possible." (New data. PALS and Complaints manager)

"In some cases, yes I do. I think that if the duty of candour was working the way it should be and as soon as there has been a negligent act the doctor said, 'I have made a mistake here. I am sorry. This won't happen again because of A, B and C' that would nip a lot of claims in the bud... there continues to be a culture of denying, delaying and then defending the cases." (New data. Claimant solicitor)

"The truth is that when I've been directly involved in things and actually spoken to patients face to face, I've never really experienced animosity. The things that happen is that when patients go home and then something goes wrong, then it just goes into the complaints procedure which is too bureaucratic. And usually if you just speak to people in person, if you give them your time, you can defuse things. It's one of the problems with this Trust in fact is that the complaints procedure is vastly over-bureaucratic and too slow so the complaints letters go through half a dozen hands and the turnaround time is weeks and it just makes things worse. Usually if you just sit down with somebody and explain face to face, you can, in my experience, you can almost always defuse the situation. But the problem with what we have here, it's because we have a massive turnover of patients and often patients go home and then they become annoyed but by that time they're at home so it's too late for us to fix whatever the problem was." (Clinical Manager Being Open Data)

Experimental studies examining the effects of communication skill on litigation and complaints are perhaps more equivocal, however qualitative work suggested that open communication, including apologies and offers of instrumental support, can resolve complaints and prevent unnecessary litigation. Respondents were also keen to emphasise that such communication has to be undertaken with great skill, as poor communication can make matters worse. Interviewees working at a policy level raised the issue of equity in regard to when recompense is discussed. While a number of participants raised this issue intimating that they would not offer compensation unless asked for it, others were concerned that if someone is harmed, the government position is they receive appropriate remedy. Views expressed in this study suggested that this does not happen consistently, despite the alignment of Department of Health and NHS guidance with Ombudsman principles that all should receive recompense where they face a situation where they are in a worse position due to the actions of the NHS. In some cases, offering financial compensation when people feel they should receive redress may well be well received, for instance if an admission is cancelled and patients are not informed or property is missing, but this has not been systematically examined. Other individuals may view offers of redress negatively and question the motives behind the offer.

"So we might give them money because we've mal-administered their complaint so we've taken too long. We might give them money for distress. We might be reimbursing things. So we might just say, 'Do you know what, we got it wrong and we're really sorry, here's £500' or something, but you've obviously got to be careful because sometimes people don't like that. They feel like they've been bought off." (New data. Complaints manager)

"We've offered something and they've taken it really badly. In actual fact the Ombudsman once asked me to pay somebody quite a large amount and I did and they were absolutely appalled and there was a lot of to-ing and fro-ing of the cheque." (New data. Complaints manager)

In the 2012 Scottish Parliament report, the settlement of a claim was reported to be influenced by a range of factors, including the level of experience of the pursuer's solicitor in medical negligence claims, and the financial value of the claim. Relatively small value claims appeared less likely to result in settlement. In those settled, the cost of dealing with the claim often exceeded the award. This research suggested that small financial claims might be better dealt with through a complaints system

permitting a moderate level of financial payment. However, their assessment of costs suggested that at best this may keep costs at a similar level and at worst it could increase costs by 50% in such cases.

4.6. Evaluation of interventions to improve risk management outcomes

The scoping review for this report identified 11 papers reporting interventions that aimed to improve the complaints/claims system and/or reduce litigation (Table 8). Five of the papers (Henrich et al., 2014; Nazione & Pace, 2015; Mello et al., 2014a; 2014b; Leflar, 2013) did not provide evidence about the impact of interventions on complaints or litigation rates. Three of these focused on implementation challenges, one reviewed evidence about different approaches and one reported which elements of 'communication and offer' programmes resulted in change. Most of the study designs are based on a simple before and after approach, which limits robustness and attribution of any change in outcomes to the intervention.

Five of the papers reported positive outcomes arising from implementation of interventions that aimed to improve claims systems and/or reduce litigation. Four of the papers reported evidence about hospital-based interventions, but one reported the impact of changes to the state legal system (Sage et al., 2016). Iwashita (2017) reported that a compensation and in-depth cause analysis scheme implemented in a hospital in Japan resulted in reduced numbers of claims being made in obstetrics. Attributing this reduction to the implementation of the scheme is not appropriate, as data reported in the paper shows that lawsuits in obstetrics were on a downward trajectory prior to its implementation.

Pettker et al.'s (2014) before and after study showed that the introduction of a patient safety programme in obstetrics was associated with changes in levels of litigation. They suggested that their patient safety programme had led to a reduction in adverse events and an improvement in the safety culture of the hospital. Perhaps not surprisingly, therefore, reduction in liability claims and in payment amounts were evident post-implementation of the programme, but the robustness of the study design is limited and this type of linear association between adverse events and litigation has been questioned in other studies.

Two papers presented findings on the impact of 'communication and compensation' schemes (Adams et al., 2014; Lambert et al., 2016). Adams et al. reviewed claims related to gastroenterology in the 10 years before and 10 years after implementation of a 'disclose, apologise, offer' scheme. In the post-implementation period, when there had been a significant rise in the number of gastroenterology encounters, evidence indicated that there were fewer lawsuits, reduced costs per claim and a shorter time to resolution when compared to the pre-implementation era. However, again the before and after design limits attribution - wider organisational and external factors might also have played some role in this reduction. The intervention was not occurring in isolation within the hospital but rather, was embedded within a system-wide commitment to quality improvement and State-level data showed that levels of litigation were already falling across the State.

Table 8: Summary of papers reporting effectiveness of relevant interventions

Reference	Type of paper	Location	Specialty	Key findings
Hendrich et al., 2014, Health Affairs	Study - assessing acceptance of and adherence to an organisational full disclosure policy.	USA	Obstetrics	<p>Not assess impact of intervention (open disclosure policy adherence) on levels or costs of litigation.</p> <p>Indicates that open disclosure is acceptable to obstetrics practitioners.</p>
Iwashita, 2017, Obstet Gynecol Sci	Study - analysis of case analysis reports	Japan (Tokyo)	Obstetrics	<p>Compensation and in-depth cause analysis is claimed to have reduced litigation.</p> <p>Questionable conclusion as the number of lawsuits were already on a downward trajectory.</p>
Sage et al., 2016, HSR	Study - Retrospective review - 1 year before and 6 years after reform	USA (Texas)	All specialties	Risk of litigation has reduced following state tort law reforms that reduced rights to sue and available damages. Thus, wider legal context can impact on the level of litigation.
Pettker et al., 2014, Am J Obstet Gynecol	Study - before and after claims	USA (Yale-New Haven hospital, Connecticut)	Obstetrics	Comprehensive patient safety initiative reduced adverse events, litigation and costs.
Giraldo et al., 2017, J Patient Saf	Study - descriptive analysis of data on medical malpractice claims held by insurance company	USA (Harvard Medical Institutions)	All specialties	<p>Following a 'disclose and apology' policy put in place at the institutions, there was no evidence of changes in volume of lawsuits over time. However, the evidence suggests that this policy was not always followed.</p> <p>Qualitative study about implementation of communication and resolution schemes in 5 New York systems. No information about effectiveness of these programmes only about challenges of implementation.</p>
Adams et al., 2014, Am J Gastroenterol	Study - before and after study of claims	USA (Michigan)	Gastro-enterology	<p>Post-implementation of 'disclosure, apology and offer' system there were reduced law suits, reduced time to resolution and reduced costs related to gastroenterology over the same time period where there had been an increase in encounters.</p> <p>However, it is important to bear in mind that this approach has to be embedded within a system-wide commitment to quality improvement. It is also important to bear in mind the context in which this is taking place - across the State there was evidence of a reduction in litigation during the same time period; and specific approaches to insurance at this hospital</p>

Reference	Type of paper	Location	Specialty	Key findings
				compared to other hospital systems across the US.
Nazione & Pace, 2015, J Health Commun	Study - scenario testing with undergraduate students on medical error related to acne treatment. (Respondents completed an online questionnaire based on the scenario given)	USA	Dermatology	<p>No intervention tested.</p> <p>Tested which factors of apology and compensation schemes (i.e. apology, empathy, corrective action, compensation) might have the largest impact on amount of money requested, negative intentions, and attitudes/anger.</p> <p>Results - Of the four elements, empathy had the greatest influence on negative intentions and attitudes/anger; corrective action had the greatest influence on attitude to physician; and apology had the greatest influence on money desired. The research showed that the main thing affecting all of these was the severity of the harm.</p> <p>Limitations: sample was college students, mainly female around 20 years only 2% of whom had experience of malpractice litigation and 50% of whom had sought medical input for acne. Other samples would be needed to assess these findings for other populations.</p>
Mello et al., 2014a, Health Affairs	Study - qualitative study reporting findings from interviews about challenges and lessons on implementation of CRPs	USA (6 medical insurance systems)	All specialties	Qualitative study about factors that might help implementation of 'communication and resolution' schemes but no information about effectiveness of these programmes.
Mello et al., 2014b, Health Affairs	Qualitative study - qualitative study reporting findings from interviews about challenges and lessons on implementation of CRPs.	USE (New York)	General surgery	Qualitative study about implementation of 'communication and resolution' schemes in 5 New York systems. No information about effectiveness of these programmes only about challenges of implementation.

Reference	Type of paper	Location	Specialty	Key findings
Lambert et al., 2016, HSR	Study - before and after analysis of administrative data	USA (Illinois)	All specialties	<p>Analysis showed that there were significant differences in the following ways post-implementation: increase in incident reports, patient communication consultations and event analyses; reduction in claims, lawsuits, costs per claim, legal fees and expenses, settlement amounts, total liability costs, self-insurance costs and time to closure.</p> <p>Reduction in time to closure and lawsuits cannot be attributed to the programme because post-implementation downward rates followed the pre-implementation trajectory.</p>
Leflar, 2013, Chest	Essay - description & evidence review of different schemes to address medical malpractice	USA	All specialties	Review of evidence about these schemes (i.e. liability-limited initiatives (since 1970s); procedural innovations to improve the dispute resolution process; move liability away from physicians to hospitals/admin no-fault compensation systems) suggests that patient compensation funds, disclosure and early offer laws, safe harbour laws, enterprise insurance and no-fault compensation could be beneficial in the US. But no new evidence presented.

Lambert et al. (2016) reported the results of a 'communication and resolution' programme on incident reports, processes within the complaints/claims process and litigation in a health system in Illinois. Their before and after study concluded that several changes resulted from the intervention: incident reports, patient communication consultations and event analyses increased post-implementation, whilst claims/lawsuits, costs per claim, legal fees and expenses, settlement amounts, total liability costs, self-insurance costs and time to closure all reduced in the post-implementation period. Again, the reduction in time to closure and lawsuits followed the same downward trajectory pre- as well as post-implementation, so attribution of these changes to the programme is not possible.

Sage et al. (2016) reviewed numbers of medical malpractice claims in a hospital (which had already enacted a 'communication and compensation' scheme) pre- and post-implementation of changes to state tort laws in Texas. These changes reduced available damages and rights to sue. This retrospective review of medical malpractice claims showed that the tort changes resulted in fewer new claims being brought against health services. Thus, this paper indicates that systems outside the organisation, such as the wider legal context in which hospitals and other health services operate, can impact on levels of litigation.

There was no evidence that a 'disclose and apology' policy implemented at Harvard medical institutions had any impact on volume of medical malpractice lawsuits (Giraldo et al., 2017).

Although some of these studies suggest that hospital/system-wide patient safety initiatives and communication and resolution programmes can reduce litigation, the clinical, organisational, and wider

legal context needs to be considered. This is especially the case when interpreting these results for national and international policy transfer. All of the authors acknowledged the specific context of the hospitals/hospital systems in which these programmes were implemented and the challenges of translating these programmes into other organisational contexts. Given the very different legal and organisational context of health care in England, further research including pilot sites in different types of health care environments would be essential to assess whether the positive impacts of these programmes are transferable to the English context. In addition, the study designs (mostly before and after without controls) limits attribution and generalisability of findings.

“I think on a very broad scale it will be helpful for people to understand what litigation does to the NHS. I would hope that if we could move to a more open dialogue when things go wrong, and we have an investigation that is robust and timely and address things and provides assurance, wherever possible, that there's been learning, again, you would see a reduction in litigation. People would feel that they have been taken seriously and that the same thing won't happen to the next patient that comes through the door. All the time you're asking your clinicians and your support staff to investigate those things, it's taking them away from their clinical time. Unless you invest in a system that means you've got a robust, independent benchmark level of investigation that is transparent and consistent across your organisation and across the NHS, you're going to get pockets of poor investigations, poor complaint responses, which are just going to fuel the litigation even further.” (New data. Legal services manager)

4.7. Can claimants be categorised?

While many participants discussed broad groups of claimants, there was little evidence in the literature or interview data that could inform a meaningful categorisation of claimants. Participants tended to group cases in the following way:

- Clear negligence
- Disputed definitions of harm
- Undesirable outcomes versus harm
- Complaints that escalate
- Speculative claims

“I think then there are, again from my experience, people who are just not happy at the outcome and people will, either because it's a late diagnosis or because the results of their treatment aren't what they expected or hoped for, think that they are owed a sum of money because of that, will pursue it just for the money. These are gut feels, these are not percentage - x per cent pursue it for this reason, x per cent pursue it for that. That's just a general feel. (Risk manager)

“I still deal with people who you know are not going to be satisfied because they will come in with a very specific attitude, I am only here under duress, I don't really want to meet with you and actually, I am going to see a solicitor. And they will come in with that attitude and it does not matter what I do or anything things will get escalated upwards. In those circumstances it tends to be things like I can't prove or disprove.” (Being Open Data. Complaints manager)

“Sometimes it can be quite frustrating because the claims process isn’t necessarily going to answer the outstanding questions that the claimants may have, and is coming on quite a long time after the event. So I’d be disappointed really if the information hadn’t previously been given. But the short answer to your question is no, I can’t really think of examples that I’ve seen that have enough common features that happen with a regularity to describe someone’s common features.” (Being Open Data. Solicitor)

“This is what needs to be made explicitly clear to the Department of Health is that there is a very extensive vetting process that has to go on and a very expensive process which solicitors go through so we are getting rid of spurious or other types of case before the Department of Health even gets to, not NHSR even gets to know about it. There will be a whole tranche of cases that disappear at that point in time. We look at it and say, ‘This hasn’t got reasonable prospects of success’. If we do feel from the statement that there are reasonable prospects of success, it’s the next stage which is getting all the person’s medical records. We have a look at those and see if the medical records back up the injured person’s version of events. Then at that point we investigate it. We often get a medical opinion and a large number of cases we go back to the person and say, ‘Look we’ve investigated and either for a plethora of reasons we don’t think we should pursue the case at this point because we don’t think you have reasonable prospects.’” (New data. Claimant solicitor)

4.8. Variation in services

While the issue of variation in services was not often explicitly addressed here it was highlighted by some as an important topic. In particular, variations can cause concerns to patients and families if they feel they are being treated differently from others in a similar situation. This can occur in a number of ways, as mentioned in some interviews.

“My sense is that we need a harmed patient pathway, so a way of managing the care of these people - and I’m talking about care, I’m not talking about just management; this is about - you know, if there were variability in any other part of the NHS, you know, these people get very little help, really - but if there was that much variability in any other area of care, there would be a patient pathway. We don’t have that for these patients, because they’re too embarrassing, they’re too uncomfortable for us.” (New data. Advocate)

This was sometimes a sense of particular organisations being more or less skilled, but some raised the issue of variable skill mix within their own organisations.

“What you find is there is local variation. Within our trust, a serious - any sort of incident investigation, whether it’s because a claim’s been brought, whether it’s a complaint or whether it’s an incident, the standard of how well that investigation will be undertaken will vary enormously across our organisation. Some clinicians will have a good insight and objectivity and will be able to look at the standard of care that was given to a patient without any conflict of interest. If they’re looking at peers management, doing a peer review of the management of patient X, they are able to do that. Other clinicians won’t have that insight and won’t be able to do that. They’ll be looking at it very subjectively and thinking about all of the other influencing factors that meant, ‘I couldn’t deliver the care to the standard I want because I don’t have enough clinic time. I don’t have the right facilities. I don’t have...’ They have a very different approach so they find it difficult to be objective.” (New data. Risk Manager)

In addition, the issue of variability was raised in relation to outcomes for families, specifically in relation to how some may be tied to or contingent on successfully demonstrating avoidable harm.

"Why would we differentiate between the child that actually you could demonstrate their birth injury, you could tenuously demonstrate that it was more likely than not that actually had the clinician done X or Y that wouldn't have occurred. You've got a disparity in what those two children's life and financial position is going to be. One's gone through a litigation process and succeeded in demonstrating it was more likely than not the harm was caused that could have been avoided, and the other child hasn't been through that process and will be not awarded. They will be relying on the state." (New data. Legal services manager)

4.9. Examples of possible good practice

In the interviews, a number of descriptions were given of initiatives or processes that appeared promising, in particular in terms of encompassing lessons learned and in addressing the recurrent theme of the importance of communication. These are highlighted by the quotes below because they aligned with what evidence does exist, or because the participants felt they demonstrated good practice:

"We offer to meet with the person if they're making the complaint, if they want, just so we can agree the terms of reference of what we're going to be investigating and looking at, what they want answers to and what they want their outcomes to be. We'll agree that with them and will investigate it. We'll let them know hopefully at the beginning if their outcomes are achievable, but recommendations during the investigation where possible and then following that we complete a report and then a response will go from the chief executive upon report completion." (New data. Claims Investigator)

"I think lots of responses now are adapted. Previously, I think there was almost a sort of blanket, 'Okay, we're going to admit liability in this. Let's move on swiftly to settle it. Here's an offer', and now I think they're investigating internally and have looked into things in detail. I do think it helps if you can say that we're prepared to admit on two points, perhaps not on something else. I think that helps to keep your consultants on side, but I think it also shows families, in those letters of response, that you have actually fully investigated their claims and the answers to their questions are there, rather than just a blanket admission, 'Let's settle it'." (New data. Claims manager)

"We do complaints training with a number of NHS trusts. So Trust X is the main one, so we do support and give training around complaints and we know as well on the helpline you can really nip a complaint in the bud informally. If the complainant, you know, is communicated with properly the person is sympathetic, all that kind of thing it can really stop the complaint moving further up as it were". (Primary Data. Independent Patient Advice helpline)

"What we've also just done, as an organisation, is we have a bereavement specialist who's working part-time, whose role is not to work directly with my complainant, but actually who is part of this role. I've fought quite hard for this. Part of her role is to review my literature, to make sure that we are saying things are saying things in a way that is sensitive, so that actually we would be more able to signpost earlier in the process. I think that's really important, because it's very difficult to absolutely resolve, 100 per cent, someone's concerns whilst they're still grieving". (Claims manager)

"When I arrived, there was a couple that, ten years later, were still grieving the loss of their relative. I know we've worked quite hard with them, and met with them. Now, that's clearly... Under the complaint regs, I could've heard, 'No, sorry, finished. Get lost, go to the ombudsman.' Some had already been to the ombudsman, but actually the caring bit of here wants to see that person move on, so we would spend a bit of extra time". (Claims manager)

5. Discussion

This project was commissioned in a context of increasing costs of litigation to the NHS. Using a combination of literature and interview data we have examined evidence about the factors that might affect litigation decisions in England.

While it is challenging to provide nuanced categorizations of claimants, three broad categories seem to emerge.

1. A group for whom medical error and adverse or unanticipated events can be life-changing in many ways. Individuals may no longer be able to care for themselves or their family and they are likely to seek compensation. This group are likely to seek compensation, and if their care has been erroneous or neglectful, should receive it. In some (but not all) cases these may be substantial claims.
2. A second, very mixed, group that may include people who have lost a family member or experienced poor outcomes and feel that their concerns are disregarded and information is withheld from them. For these people, this can begin a long search for answers that becomes a life's work and has severe financial, emotional and health costs.
3. A final group who due to an increased awareness of rights and improved access to no or low risk legal representation pursue a legal claim in response to harm or loss.

Current systems for seeking compensation are at times costly and protracted; nevertheless, people pursue litigation for various reasons. The limited evidence available suggests that in addition to the degree of harm, many factors can sway people's decisions about whether or not to take legal action, and considerable uncertainty remains around what affects these choices.

Fundamentally, we know little about the trajectory of concerns, complaints and claims. Data systems within organisations are largely geared to examine safety and are more uniform and capture moderate to severe adverse events. Data collection around complaints and claims happens in parallel with data collected on incidents and harm. There are examples of attempts to make these systems work more closely together, but they are by no means consistent or universal. This may mean valuable lessons that might inform how complaints are handled to avert expensive and protracted legal cases may be missed.

Within current systems, from the limited evidence available, it appears that many claims never appear as complaints. This may signal missed opportunities to address those individuals' issues at an earlier stage. While this may not avoid litigation altogether, it may avoid some claims and reduce costs in others. The evident challenge is the ability to identify potentially unhappy or harmed patients early, to address situations that reflect concerns about poor outcomes. The current PALS and complaints system seem to either fail to capture this data or fail to share data systematically in informing later claims.

In some areas of care, when an identifiable event occurs, this may trigger a complaints process or instigate a mechanism around duty of candour, which may allow organisations to deal with potential claims and try to prevent further claims by improvements from the lessons learned from safety

initiatives. This does not address all potential situations, however: many patients raise concerns and complaints about areas that are not readily classifiable within organisationally defined harm or safety dashboards. In many of the powerful accounts of patients from the Being Open study, it was often in cases where harm was contested that the most distressing stories emerged. Simply concentrating on areas of reporting requirement may lead to significant future problems.

The pilot study highlighted by NHS Resolution suggests there are potentially lessons to learn from closer communication between internal systems for raising concerns. Qualitative findings from both the Being Open data and this report consistently suggest that skilled communication in the early stages of complaints and concerns could avert progression of some cases to claims. Some of these may not constitute a case but are often in areas of less certainty for both claimant and NHS Resolution. It is important to determine why claimants circumvent complaints processes.

International research evidence indicates that greater transparency in healthcare and greater skill in communication may avert some claims, but there is little concrete evidence to support transferability of such schemes to England. The GMC claim that saying sorry can often avoid a complaint – but we know that many claimants do not pursue a complaint prior to making a claim. As such, it is possible that this could reduce complaints but not claims. Training health care professionals and those working in the complaints system in enhanced communication skills, with a particular emphasis on honest, empathetic communication, might not necessarily minimise litigation (the evidence for better communication reducing litigation is inconclusive, at best) but it may improve the claimant's experience of the process and help maintain trust in health care staff and organisations.

There were a variety of views on how closely aligned teams dealing with concerns, complaints and risk should be. In some organisations, closer links were being established in an attempt to make services seem seamless for patients. In contrast, in other organisations this had been tried but abandoned, as it was felt more credible for PALS, complaints and risk management to be independent, despite some increased delay.

There are a number of examples of No-Fault Compensation Schemes, but worldwide systematic review evidence suggests that we should proceed with caution when interpreting findings of papers from international contexts - substantial differences across liability environments, clinical specialities, funding and provision of subsequent health and social care and geographical locations mean they may have limited transferability. It may be possible, however, that alongside sensitive conversations, initial offers of material assistance may help to maintain relationships and build trust in the organisation when events are unanticipated or result in adverse outcomes, but the evidence base for reform is limited.

Much of the qualitative data highlighted a strong sense that patient and carer-facing conversations could be improved, and systems could work more closely to monitor patterns and outcomes. The environment of healthcare litigation is complex, and changing it is likely to require a complex intervention. Future research would need to involve both legal and health research collaborations, taking into account the perspectives of patients, professionals and organisations as well as the possible legal frameworks that may be affected by any changes. There is little research to inform underpinning

logic models for changing behaviour of patients and families in interacting with systems designed to capture complaints or for professional responses to complaints.

It is important to acknowledge that the work reviewed here represents literature framed in the context of health services research. There is a large volume of legal literature which has not been included. The synthesis of health and legal perspectives is an important step needed to address further the rates of litigation within the NHS and particularly to explore cross-jurisdictional issues.

While the limitations of the data and the complexity of picture of litigation drivers should not be underestimated in exploring the trajectory of target intervention points, we have tried to identify how these might be determined, and how the research agenda could be progressed. While there were no clear solutions, we have highlighted a number of areas and stages where it may be possible to focus future work to monitor patterns of litigation, improve the experiences of patients, families and staff, and potentially prevent cases or reduce protracted legal cases. These are illustrated in table 9, but all are speculative at this stage, and require detailed development, testing and evaluation.

Table 9: Framework of stages and actions implicated in improving litigation outcomes

Stage	Possible Action	Who	Support Needed
Clear Error and Harm	Continue to engage in effective safety initiatives. Align safety and risk management more closely. Involve families more in investigations. Prompt apologies and potential for early offers of instrumental support for families. Consider no-fault compensation schemes.	Clinical staff Governance/ Safety Leads NHS Resolution	Communication support training for disclosure. Disclosure coaching. Institutional experts in disclosure. Public awareness campaign to clarify poor outcome and neglect.
Low level distress, dissatisfaction identified by clinicians/nurses	Address with the patient/family to prevent escalation	Clinicians/nurses	Better training for clinicians in customer service.
Issue raised with PALS	Involvement of staff mediated by PALS	PALS/ clinical staff	Closer communication between PALS and ward staff/ frontline staff Customer service training Closer alignment between PALS/Complaints
Issue escalated to complaint or passed to complaint by PALS	Consider whether complaints should be dealt with by clinical staff. Ensure specialist resolution training for complaints managers.	Clinical staff. Complaints managers	Closer communication between PALS and complaints. Closer communication between complaints and staff. Consider best approaches to individual cases. Skills training in identifying signs of escalation and techniques to deal with conflict. Consider visiting families at home.
Claims	Consider development of mediation with families and claimant solicitors. Address claims where liability is accepted quickly and offer compensation promptly. Consideration of reform.	Complaints managers. NHS R Claimant solicitors Specialist clinical staff.	Closer working between legal and clinical agendas. Political debate. Research to determine effects of all possible reform options in relation to claims in the UK context. Public consultation.
System wide change	Clearer tracking of concerns, complaints, claims to identify patterns and improve learning	NHS NHS Resolution PALS	Improved data capture. Improved data sharing

6. Conclusion

There is a significant literature exploring litigation, particularly discussing likely factors which may affect the trajectory of claims. Those directly involved in complaints and litigation have strong opinions on the causes and potential ways to address them, but there is little definitive underpinning theory or rigorous evidence on which to base interventions or policy. Lessons may be learned from the overseas experience (particularly in the US) about the implementation of a policy of open disclosure, but this may not be generalisable, and the clinical negligence context and experience in each country will have implications for how open disclosure is perceived locally.

Interviews in this study confirmed a general perception that, while some individuals litigate to address the real financial consequences of significant harm, others litigate when they fail to resolve unanswered questions about their care, particularly to get information when this is perceived to have been unavailable through routine contacts with professionals and organisations. There is, therefore, continued emphasis on improving transparency and communication in relation to complaints, despite little empirical evidence of the effectiveness of communication alone preventing progression to claims.

There were differences in the views expressed relating to motivations to litigate between professional groups, between individuals within groups, and even contradictions in individuals own expressed views within the same interview. This makes it challenging to draw general conclusions without considerable further study.

Despite a considerable policy narrative, from international and UK sources, that financial recompense may not be the dominant driver of many claims, it is clearly one important motivation. While interview participants supported the notion of just recompense for harm, they also noted increasing numbers of people willing to explore claims for events that may have previously been considered as relatively benign. In addition, since litigation may be driven to some extent by anticipated future costs of health and social care, funding constraints in both sectors could exacerbate concerns, and drive increasing rates and levels of litigation.

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Appendix 1: Interview topic guide

About you

- What is your role and how long have you been in the position?

Clientele

- What type of cases do you deal with?
 - Clientele?
 - Complaints?
- What factors make someone escalate from complaint to litigation?
- Vice versa

Why do people litigate?

- From your experience, what factors affect why people litigate against the NHS
 - What purpose does it serve
 - What do people want from the process
- Could their needs/wants be met outside of litigation?

Typical case

- Without going into specific examples, can you talk me through a typical case that you might see?
 - Initial contact
 - Collecting evidence
 - Negotiation
 - Court processes
 - Determining compensation payments

What are the costs of litigation?

- From your experience, what are the costs of litigation?
 - When winning and when losing
 - Financial
 - Emotional
 - Other

Trends in litigation

- Have you noticed any changes in the cases you are dealing with over time?
- If so,
 - in what ways
 - what do you think explains these changes

Is there anything else that you would like to tell me?

Appendix 2: Editorials and commentaries

Table A2-1: Editorials related to study reports

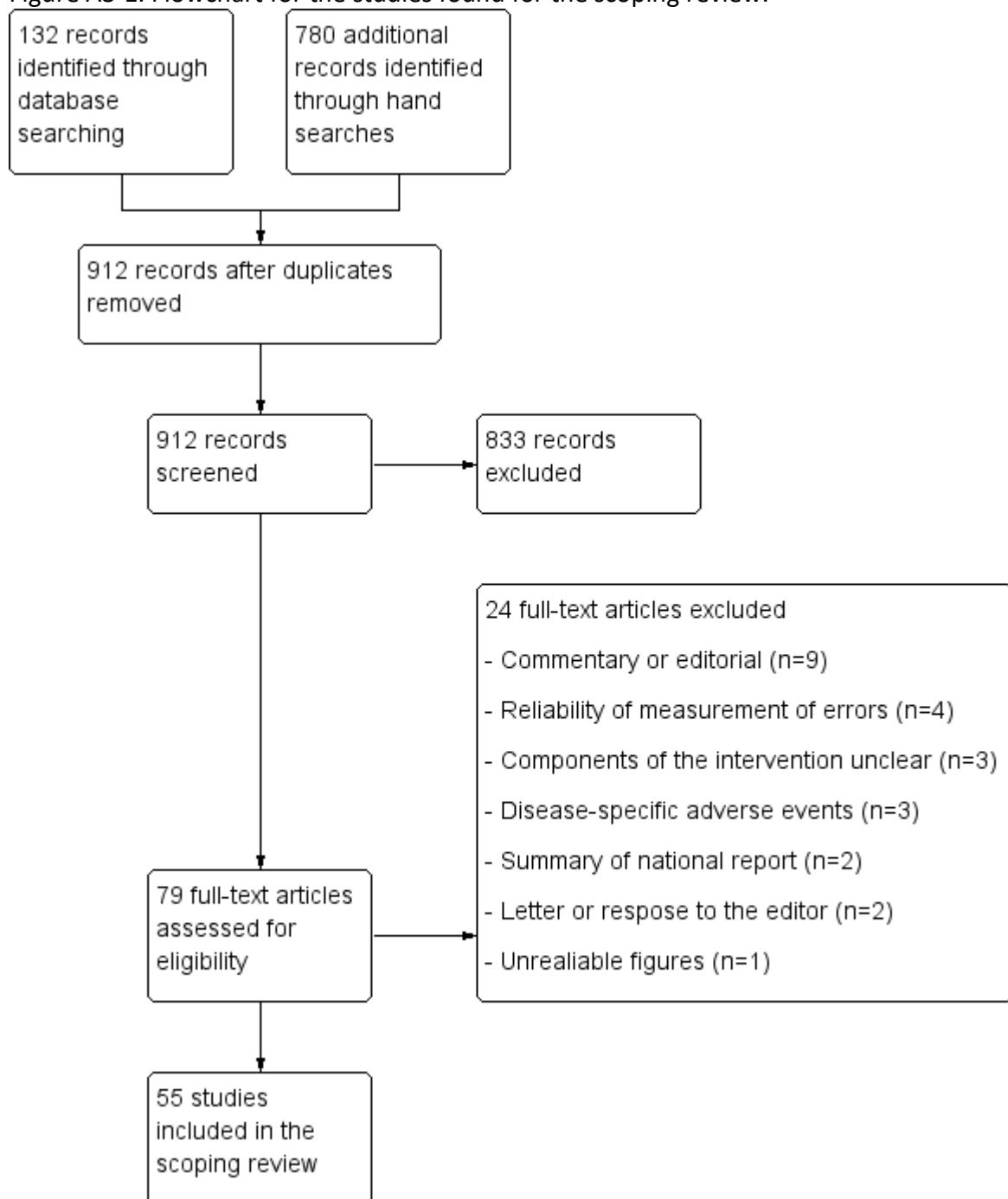
Commentary	Paper critiqued	Topic	Critiques
Adhikari, 2013	Jha et al., 2013	Adverse events.	Preventability of events was not considered. Contextual issues not fully discussed (i.e. access to some interventions). Not distinguish between DALYs resulting from AEs and those that would have occurred due to underlying condition.
Shojani & Thomas, 2013	Baines et al., 2013	Adverse events	Suggest that rates of preventable AEs reduction should not be used as a proxy for improvements in patient safety because of difficulties in determining preventability and classifying adverse events
Sarker, 2016	Panesar et al., 2015	Patient safety incidents	Suggest that the study undercounts incidents because only events where the wrong thing was done were included. The authors did not include events where the right thing wasn't done.
Shojania & Mheen, 2015	Baines et al., 2015	Adverse events	Similar critique to that made by Shojani & Thomas, 2013.

Table A2-2: Summaries of national reports on trends related to litigation

Summary	National report summarised
Anderson, 2013, Clinical Risk	NHS Litigation Authority, 2012, Ten Years of Maternity Claims – An Analysis of NHS Litigation Authority Data. London: NHS LA (outside the timescale for this study)
Neville, 2017, The Financial Times	National Audit Office, 2017, Managing the costs of clinical negligence in trusts. London: NAO

Appendix 3: Flow chart for the scoping review

Figure A3-1. Flowchart for the studies found for the scoping review.



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REsearch**