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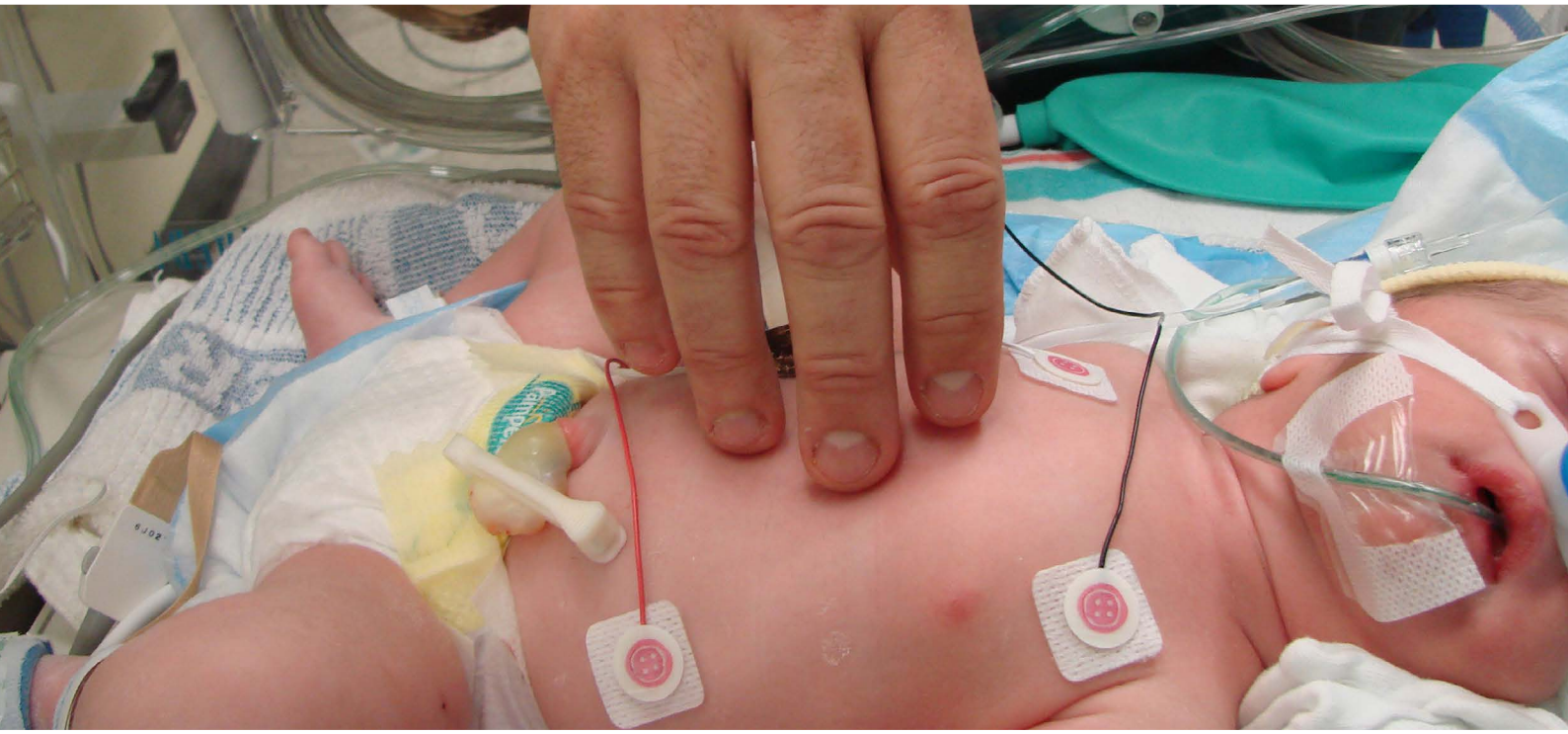
No-Fault Compensation Schemes

A rapid realist review to develop a context, mechanism, outcomes framework



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There were no conflicts of interest in the writing of this report.

Contributions

The opinions expressed in this publication are not necessarily those of the EPPI-Centre or the funders. Responsibility for the views expressed remains solely with the authors.

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Contents

Abbreviations

ACC	Accident Compensation Corporation (New Zealand)
CMO	Context, mechanisms and outcomes
DH	Department of Health (England)
NFCS	No-fault compensation scheme
NHSLA	NHS Litigation Authority
RQ	Review question

Guidance on type of review and how to read this report

Methodological approach

This report presents the findings from the first part of a realist review. The review uses systematic methods to identify and critically assess study relevance to inform the development of theories about how a complex intervention, such as compensation schemes for injury, might operate. The theories take the form of 'context', 'mechanisms' and 'outcomes' (CMO) configurations seeking to provide explanatory accounts of what compensation schemes might look like and how they might work. The text describing each CMO configuration is the theoretical and empirical justification for the proposed theories, representing a transparent argument based on the literature identified. The second part of a realist review, not undertaken here, seeks more definitively to answer questions about the effectiveness of each CMO configuration proposed. As a type of systematic review, the purpose of this first half of a realist review is to develop readers' thinking about what CMOs might affect outcomes. It is a review which generates theories about why something might work or not; however, it does not seek to establish whether an intervention is effective or not.

Our searches focused on finding a variety of explanations for the observed outcomes, but we did not seek to include studies that repeated these explanations. These excluded studies could be brought together to establish the validity of the explanations in the second stage of the realist process. Accordingly, our included studies were not assessed for their risk of methodological bias, since we were not aiming to validate causal relationships. Like any type of qualitative research synthesis, a realist review seeks to consider critically the salience of study findings; i.e. the contribution each study makes to the review question in terms of variety of examples (richness) and exploration of meaning (depth). In a systematic review designed to generate theoretical hypotheses, this type of critical assessment of studies is argued to be more appropriate (Carroll and Booth, 2015; Lewin et al., 2015; Mays and Pope, 2000).

Scope of the review

This review was commissioned by the Department of Health, London with a policy focus primarily on the introduction of an administrative compensation scheme relevant to injuries occurring during birth. However, due to a lack of policy and research literature specific to this area, much of the evidence is drawn from compensation schemes concerned with other types of medical and non-medical injury. Thus, some of the findings are not directly transferrable to birth injury. Furthermore, the review's primary focus is compensation schemes which do not require claimants to establish fault; however, the review also extends to compensation schemes which provide an alternative to litigation based on the principles of 'no fault', 'no blame' or 'avoidable harm'.

Report structure

As this is the technical report of the first part of a realist review, using transparent methods, some sections of the report are necessarily detailed. Without compromising on the transparency that is expected of a systematic review, we have structured this report

to help those who are more concerned with the findings than the methods. Therefore: the report is organised in three sections:

1. **Evidence summaries**: A two-page abstract and an executive summary of the key findings
2. **Part I:** This contains the CMO theories in full (chapter 3), preceded by the background, aims and a brief section on methods (Chapters 1-2). Chapter 3 also includes an overview of the papers informing the review. The findings are presented in turn for each outcome, and include a hypothetical statement of the context and mechanisms thought to influence outcomes. Part I concludes with a summary of the CMO configurations, in addition to the strengths, limitations and implications of the review.
3. **Part II** contains additional detail about the methods and how papers were identified, screened for inclusion and examined in the review, as well as appendices that contain further details of the papers, the review's search strategy and the coding tools used.

Structured Summary

What do we want to know?
At present in the UK, compensation for medical injuries can be sought through tort litigation, with payouts made through court or out-of-court settlements. No-fault compensation schemes (NFCSs) can provide an alternative method to redress claims resulting from medical injury. To inform consideration of an administrative compensation scheme relevant to birth injuries, we sought to develop preliminary theoretical frameworks describing the mechanisms that might influence engagement in such schemes and lead to improvements in outcomes for affected individuals and families. We conducted the first part of a realist review, which seeks to identify empirically and theoretically-based contextual, mechanism and outcome (CMO) configurations. We did not test the CMO configurations, so no causal claims are made. Thus, the findings should be read in this light, and should not be interpreted as definitive evidence that the CMO configurations presented below *do* influence engagement or outcomes.

What did we find?
We drew on 44 papers relating to medical and non-medical injury, to present a summary of possible mechanisms entailed in no-fault compensation and tort reform that are thought to lead to patient and clinical practice outcomes (see Table A).

Table A: Context mechanism outcome configurations

Outcomes	Context and mechanism potentially influencing outcomes
Justice 1: Access to courts	To make compensation schemes attractive to claimants, they must *offer payment* and *broader eligibility criteria*, to ensure schemes remain more appealing than the tort-based system.
Justice 2: Equality of access	NFCSs that are *free to access* improve justice outcomes in that they are *accessible to all eligible parties*, unlike the tort system, which favours those who can afford legal representation.
Justice 3: Transparency of process	Transparency of process achieves justice through the *representation of the claimant*, and mechanisms that improve the *consistency of decision making through the use of medical experts* and the consideration of precedents.
Justice 4: Compensation decoupled from disciplinary procedures	*Creating a 'Chinese wall'*[1] *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 NFCSs *reduce unnecessary tests and procedures* and *improve access to health care for patients considered 'riskier' by clinicians*, because doctors are less likely to practise positive and/or negative defensive medicine[2] to protect themselves from litigation.

[1] *A barrier that separates two or more groups, usually as a means of restricting the flow of information*

[2] *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 'riskier' by clinicians.*

Outcomes	Context and mechanism potentially influencing outcomes
Patient safety 1: Admitting to error	NFCSs 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	NFCSs 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	NFCSs and tort reform improve the physical health of patients by *shortening the length of time to claim closure and by including a rehabilitative element in the award*.
Health 2: Mental health	NFCSs and tort reform 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*.

- Overall, we found varied conceptualisations of NFCSs in different geographical contexts, and papers that discussed the effects of tort reform with comparable effects.
- Liability was the key variable in schemes, with the concept of 'blame' shaping those schemes:
    - In **France**, the compensation scheme was an expression of solidarity with individuals who had suffered major injury (Barbot et al. 2014) but retained the notion of blame and the litigation process for those patients who could establish liability.
    - In **New Zealand**, the scheme operated like a targeted social security benefit programme with its broad eligibility criterion of 'treatment injury' (Kachalia et al. 2008).
    - In the **United States**, tort reform seemed to be the reluctant consequence of a breakdown in the compensation system when doctors could no longer afford the insurance premiums and were leaving the profession (Kessler n.d.).
- There is evidence to suggest that the schemes were a product of their jurisdictions. For example:
    - In **New Zealand** and **Scandinavia**, the creation of a state-run compensation scheme fitted with their conception of health care as an important provision by central government.
    - In the **United** States, there was understandable reluctance to deny claimants the possibility of attaining damages through the court process, since there was less of a social security safety net to support individuals with ongoing ill health and disability.
- The empirical research attempted to test the effect of no-fault schemes and tort reform as outlined in Table A. The findings from this research underpinned propositions to explain the observed effects of no-fault schemes and tort reform. These propositions suggested reasons for:

  - more precise targeting of compensation to reach beneficiaries (Davis et al. 2002)
  - possible impacts on physical and mental health outcomes (Cameron et al. 2008; Montgomery et al. 2015), and health system costs (Vandersteegan et al. 2015)
  - more equitable access to justice (Bismark et al. 2006a, 2006b) and health care (Dubay et al. 2001), and the importance of procedural justice (Siegal et al. 2008).
- However, the schemes should not be considered a panacea, as doubts remained as to their contribution to patient safety and provider accountability (Wallis 2013).

What are the implications?
The CMO configurations generated from the studies contribute to our understanding of how compensation schemes can benefit patients and health professionals. Benefits of schemes include improved targeting of compensation to those most deserving of it, and speedier physical recovery after injury. However, the complexity of the interactions between compensation processes, individual circumstances and context-specific health systems make it difficult to establish strong potential causal pathways, most notably regarding health outcomes. Overall, the shape of compensation schemes will be highly influenced by the health system context and the prevailing political opinion about the role of the state in health care.

How did we get these results?
Papers were sought via iterative searching and included if they focused on compensation schemes relevant to iatrogenic injuries occurring at birth or in the early years (under five years of age), or sought to compensate injuries in two out of three of the following cases: i) resulted high-value claims; ii) had high long-term costs; iii) were highly emotive to victims. Papers were assessed for their relevance: the quality of the research reports lies in the richness of the descriptions of CMO interactions. Descriptive and empirical data were extracted and analysed from individual reports by two reviewers. They met to discuss the findings and agree the final set of CMO configurations, and text to justify them, as presented.

Executive summary

Background

At present in the UK, 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 (NFCSs) provide an alternative, and perhaps more egalitarian method to redress claims resulting from medical injury. A range of injury compensation schemes have been instituted in other countries for injuries acquired at birth (Farrell et al. 2010) or as a result of medical or other non-medical related injuries (Cardoso et al. 2015). Characteristics common to such schemes include: eligibility and threshold disability criteria; financial caps and/or limits to the extent and type of cover provided; levels of entitlements; levels of access to justice; restricted court access; and the existence of a comprehensive national social welfare/social insurance system (Farrell et al. 2010). However, the extent to which the context of compensation affects whether such schemes are taken up by affected families is not known. Such contexts include societal factors, the health care system, the type of precipitating event, or the characteristics of those who institute claims.

A key policy concern in England is compensation for birth-related trauma. Maternity services comprise one of the areas of 'highest clinical negligence claims' in terms of both number of claims and costs reported to the NHS Litigation Authority (2012 p.4). 'Between 2000 and 2009, over 5,000 claims were made totalling £3.1 billion' (NHS Litigation Authority 2012, p.4). This represents less than 0.1% of all births in England during a similar period (NHS Litigation Authority 2012). An administrative compensation scheme for birth injury does not exist in the UK at present, although there are schemes in place for other health issues, such as vaccine-related injury.

Review aims and approach

This review was commissioned to inform considerations around the potential to develop an administrative compensation scheme for medically acquired birth injury in England. The overall aim was to develop preliminary theoretical frameworks of the mechanisms that might influence engagement in 'no-fault type' compensation schemes and that might influence outcomes for affected individuals and families. A realist review was chosen as an appropriate method as it is specifically designed for analysing information on varied and complex interventions implemented across more than one context and policy area, and because a realist approach can be used to explore the suitability of interventions for particular circumstances or to refine interventions for different contexts (Rycroft-Malone et al. 2012). We employed iterative realist methodology to answer the following research questions:

Review question 1: *What individual or contextual factors contribute to people's reasons and motivations for engaging in no-fault type compensation schemes after medical injury? (RQ1)*

Review question 2: *How are no-fault compensation schemes thought to improve outcomes for people with medical injuries? (RQ2)*

To fit with a time-restricted policy window this review focused on answering these questions by conducting the first part of a realist review: identifying empirically and theoretically-based contextual, mechanism and outcome (CMO) configurations. We did not test the effectiveness of each CMO configuration proposed (second part of a realist review). The review follows the publication standards suggested by the Realist and Meta-Narrative Evidence Syntheses: Evolving Standards (RAMESES) project (Wong et al., 2013; see Appendix 1) and indicates where modifications were made to fit with the short policy time-frame (December 2015 to April 2016).

In relation to the scope, it should also be noted that the review considered papers exploring no-fault type schemes, or schemes which provide an alternative to litigation based on principles of 'no-fault', 'no-blame' or 'avoidable harm'. In addition, although this review has been developed with a particular focus on relevance for birth injury, much of the evidence identified was drawn from other types of compensation schemes, and therefore some of the findings are not directly transferrable to birth injury, although they provide helpful insights.

Methods

By conducting the first part of a realist review, the aim was to help readers think through what possible mechanisms might affect outcomes in the context of NFCSs. We sought to develop hypothetical context-mechanism-outcome configurations (CMOs). The text describing each CMO configuration is the theoretical and empirical justification for the proposed theories, representing a transparent argument based on the literature identified. It is important to read the findings with these aims and objectives in mind. We did not aim to establish causal relationships between possible mechanisms and outcomes, and so did not appraise methodological aspects of study quality. Instead, we assessed the quality of the study reports in terms of their contribution to the review's findings, i.e. the richness of descriptions of these interactions.

We met regularly with the Department of Health (DH) policy leads throughout the review process to ensure that the review remained closely aligned with their needs and emerging policy requirements. Papers were sought via iterative searching and included if they focused on no-fault compensation schemes relevant to iatrogenic injuries in children occurring at birth or in the early years (under five years of age), or sought to compensate injuries that had at least two of the following characteristics: i) resulted in high-value claims; ii) had high long-term costs; or iii) were highly emotive to victims. Empirical and descriptive data were extracted from individual studies and were assessed according to the way different mechanisms appear to influence outcomes.

The initial conceptual framework guiding the review was based on the key features of NFCSs for medical injury identified in the review by Farrell et al. (2010 pp.8-9). These include: eligibility and threshold disability criteria; limitations to the extent of cover; levels of entitlements; simpler and more comprehensive access to justice; restricted access to courts; and the existence of a comprehensive national social welfare/social insurance system. The review began by taking these key features and reading some key studies to develop initial hypothetical configurations between) contexts, i.e. different types of compensation schemes implemented in different jurisdictions (O'Campo et al. 2015); mechanisms, e.g. factors potentially contributing to claimant engagement in

schemes, or other types of mechanisms triggered by the ways compensation schemes might be designed and implemented; and outcomes (e.g. access to justice, health).

We developed some initial CMOs relating to claimant experience by looking at reviews that discussed compensation policies. These CMOs became the initial conceptual framework for the study, and we asked the policy team at the DH to prioritise those they would like to investigate further. This discussion informed the later searches, where we used the data extraction and analysis stage to refine, confirm or refute these configurations. After these initial conversations, the team indicated an interest in outcomes for clinicians relating to clinical practice, patient safety and clinician well-being. We went through the same process of developing crude CMOs to prioritise and narrow our later searches. The stages of the CMO development for claimants and clinicians are documented in more detail in Part II, the technical report. Descriptive and empirical findings were extracted and combined to generate a justification to support the generation of each CMO. Through discussions and individual analyses, reviewers focused on refining each CMO to be as practically specific as possible. Subsequent analysis of the studies against these CMOs aimed to clarify and substantiate our thinking about why we had structured the CMOs in this way, acting as a further justification and rationale for the presentation of the final configurations.

Summary of key findings

There was a lack of evidence directly answering the first review question, on the individual or contextual factors potentially contributing to people's reasons for taking up the offer of an NFCS either after birth or other types of medical injury. To answer the second review question, we drew on 44 papers to present an overview of proposed mechanisms entailed in compensation schemes thought to lead to patient and clinical practice outcomes. The majority of papers were empirical studies (n=33). The remaining 11 papers were policy reviews, which compared different policies across jurisdictions, drawing on empirical data, and discussed key variables, such as liability, which became an important component of many of the mechanisms. Please note that, as mentioned above, the aim of this review was to develop preliminary theoretical frameworks of the mechanisms that might influence engagement in NFCSs; the findings should be read in this light, and should not be interpreted as definitive evidence that all these mechanisms definitely *do* influence engagement.

Key features of no-fault compensation schemes identified in the papers

The components entailed in NFCSs for medical injuries vary across high income countries. The main differences focus on the definition of eligibility criteria to determine fault and how schemes are funded and organised. An overview of the different approaches to compensating people who have experienced a medical injury is provided in Table B.

Table B: 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 of employable age
Continued access to courts	No	Yes	Yes	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 non-economic damages	Economic and non-economic damages	Economic damages

* Schemes operating in Australia are omitted as they report non-medical compensation schemes
†Drawing on two no-fault birth injury schemes available in Florida and Virginia
†† Nordic countries include Sweden, Denmark, Norway, Finland and Iceland, with specific details of schemes varying across countries

NFCSs specifically for neurological birth injury are in place in **two US states**: Florida and Virginia; other countries operate NFCSs for a range of medical treatments.

The US-based birth injury schemes insist that, to be eligible, the birth injury has to be the result of the birth process and they exclude injuries caused by genetic or congenital abnormality.

France has implemented two systems: a no-fault standard for serious and unforeseen medical injuries; and a fault standard, where access to the courts remains fully available.

The Nordic countries operate an 'avoidability' standard, compensating patients who have experienced injuries that could have been avoided under optimum conditions, for example, where the injury would not have occurred under the care of the best health

practitioner/system. Here it is referred to as the 'experienced specialist' rule. An administrative scheme is in place to provide patients with a non-litigious route to compensation. Claimants have the right to appeal a decision made by schemes. They can also appeal to the courts if dissatisfied with the outcome of that appeals process and/or directly pursue a tort-based claim.

New Zealand has put in place the broadest eligibility criteria, with a no-fault standard applicable to any unexpected treatment injury.

The only scheme to operate without a financial cap is in **France** and **all but the New Zealand** schemes aim to cover both economic and non-economic costs.

Summary of context, mechanisms and outcome configurations
As stated, our review aimed to develop preliminary theoretical frameworks of the mechanisms influencing engagement in NFCSs. Using a realist approach, we sought to understand the connections through which different components of such schemes, operating under certain social and political systems, are thought to influence patient and clinician outcomes. This section presents a summary of our context, mechanism and outcomes (CMO) configurations based on our analysis of the papers. The CMOs are organised according to four main outcome categories identified in the literature and prioritised as of interest to policy leads consulted during this review: 1) access to justice; 2) clinical practice; 3) patient safety; and 4) patient health.

We conceptualise context as the jurisdiction of the policies under study and, for this reason, have indicated which countries we are discussing in our CMOs. We draw on the sociological work of Esping-Andersen (1990) to typify the welfare state context of the policies. Therefore, the social democratic nations of Scandinavia appear to favour a greater role for the state in providing for their citizens due to their political history of social protection. Thus their welfare model explains the development of compensation schemes as an extension of that protection. The more liberal states, such as the USA, can be seen to favour a more individual response to treatment injury, only stepping in when the market fails to provide essential services. This explains the move to cap damages when doctors were leaving the profession due to high insurance premiums (Kessler n.d.). New Zealand, with one of the most advanced compensation schemes, is also a liberal jurisdiction according to Esping-Andersen (1990). This suggests that its welfare model is closer to the USA than Sweden and would favour the tort system. However, like Australia, it has a strong trade union tradition (Esping-Andersen 1990) and it is notable that its compensation system started as a worker compensation programme and continues to support only those in employment today. Finally, France represents the conservative state (Esping-Andersen 1990), and its compensation programme leaves the majority of claimants to pursue redress through the courts, as in the liberal states, but recognises an obligation to those in particular need. Therefore, in a spirit of solidarity (Barbot et al. 2014), its system compensates those suffering unpredictable injuries and those with severe injury.

Very few papers relate directly to compensation for birth injury but we have included those papers that describe mechanisms relating to medical injury, worker compensation and road accident insurance where the notion of no-fault affected outcomes. We argue that in our exploration of this mechanism of 'no-fault', looking at the broadest range of circumstances enables a fuller picture of the possible effects of NFCSs. The mechanisms

outlined below are derived from the evidence found in the studies we included. We do not offer an assessment of the strength of the evidence but aim to describe fully what explanations exist for the patterns of effect observed in the literature. This allows policy makers to understand the possible implications of such a policy on the introduction of a compensation scheme, if it is implemented, but also acknowledges the complexity of the political, social, health and legal systems which this policy will operate in and be affected by. We make no claims about causal links, since establishing causality was not the aim of this review and would possibly be highly challenging in such complex and diverse contexts.

Access to justice

Four distinct 'access to justice' outcomes were identified in the literature. These outcomes focused on: the extent to which schemes are more appealing than accessing the court; ensuring equality of access to compensation schemes; processes related to the transparency of schemes; and the importance of ensuring that compensation schemes are decoupled from disciplinary procedures (see Table C). The 14 papers providing information on these outcomes represent six policy contexts cited in this review (the USA, France, the Nordic countries, Australia and New Zealand).

Table C: Access to justice

Context	Mechanisms	Access to justice
USA: Early-disclosure and resolution schemes **France:** Fault/no-fault schemes **Nordic countries**: Avoidable standard / unavoidable injuries **Australia:** Fault/no-fault schemes **New Zealand:** No blame compensation schemes **International:** Tort reform/litigation	To make compensation schemes attractive to claimants, they must offer payment and broader eligibility criteria, to ensure schemes remain more appealing than the tort-based system.	Justice 1: Access to courts
	NFCSs that are free to access improve justice outcomes in that they are accessible to all eligible parties, unlike the tort system, which may favour those who can afford legal representation (in certain jurisdictions).	Justice 2: Equality of access
	Transparency of process achieves justice through the representation of the claimant, and mechanisms that improve the consistency of decision making through the use of medical experts and the consideration of precedents.	Justice 3: Transparency of process
	Creating a 'Chinese wall' 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.	Justice 4: Compensation decoupled from disciplinary procedures

Clinical practice

This section explores the mechanisms under which tort reform and no-fault compensations schemes are thought to lead to improvements in clinical practice outcomes (see Table D). Of the 14 relevant papers, the majority draw on the medical-legal context in the USA (n=9); further studies add to our theoretical understanding by drawing on wider international contexts of compensation schemes and tort reform (n=5).

Table D: Clinical practice outcomes

Context	Mechanisms	Clinical practice outcomes
USA: Tort reform / litigation only **International:** No-fault schemes/litigation	Tort reform and NFCSs reduce unnecessary tests and procedures and improve access to health care for patients considered 'riskier' by clinicians, because doctors are less likely to practise positive and/or negative defensive medicine to protect themselves from litigation.	Clinical practice 1: Defensive medicine

Patient safety

The conditions under which patient safety can be improved as a result of tort reform and/or the introduction of NFCSs are drawn from 10 papers. The two key outcomes identified in the literature focus on how different mechanisms can support clinicians to more readily admit to errors and the extent to which mechanisms can be put in place to enable learning from those errors (see Table E). Just over half of the papers reflect on the introduction of an NFCS in New Zealand (n=4) or schemes currently available in the Nordic countries (n=2).

Table E: Patient safety outcomes

Context	Mechanisms	Patient safety outcomes
USA: Early-disclosure and resolution schemes **Nordic countries:** Avoidable standard / unavoidable injuries **New Zealand:** No-blame compensation schemes **USA:** Tort reform / litigation only	NFCSs 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 1: Admitting to error
	NFCSs 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.	Patient safety 2: Learning from error

Health outcomes

All of the studies (n=8) associated with health outcomes are concerned with compensation relating to accidents, mostly road traffic; with none related to iatrogenic injury (see Table F). Some are concerned with accidents at work and are covered by worker compensation schemes. Most of these studies were conducted in Australia (n=6).

Table F: Patient health outcomes

Context	Mechanisms	Health outcomes
Australia: Fault/no-fault schemes **New Zealand:** No-blame compensation schemes	NFCSs and tort reform improve the physical health of patients by shortening the length of time to claim closure and by including a rehabilitative element in the award.	Health 1: Physical health
	NFCSs and tort reform 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.	Health 2: Mental health

Key mechanisms influencing outcomes

We found few papers that directly answered our research question about the factors that affected take-up of these schemes by patients affected by medical injury. However, our exploration of the mechanisms associated with no-fault schemes gives us some information about the possible motivations of patients and clinicians to engage with such schemes. So in answering question two, we have provided some understanding about question one.

Overall, we found varied conceptions of the notion of NFCSs. We also identified and included papers that discussed the effects of tort reform when those effects were comparable to no-fault schemes, for example, where the effect of reduced malpractice pressure on doctors and the subsequent impact on defensive medicine were similar to mechanism in no-fault schemes of the decoupling of compensation and disciplinary procedures (Vandersteegen et al. 2015).

Liability was the key variable in the schemes and the concept of blame across different jurisdictions shaped the schemes profoundly. In France, the compensation scheme was an expression of solidarity with individuals who had suffered major injury (Barbot et al. 2014), but they retained the notion of blame and the litigation process for those patients who could establish liability. In New Zealand, the country that most clearly dispensed with blame, the scheme operated like a targeted social security benefit programme, with its broad eligibility criterion of 'treatment injury' (Kachalia et al. 2008), but only for those in employment. In the United States, tort reform seemed to be the reluctant consequence of a breakdown in the compensation system when doctors could no longer afford the insurance premiums and were leaving the profession (Kessler n.d.). These reforms seemed highly contested, with studies competing to show that the reforms had large or no effects. This research may reflect an anxiety about reducing the accountability of the medical profession, and restricting access to legal redress.

Evidently, the schemes were a product of their jurisdictions. In New Zealand and Scandinavia, with their universal health-care provision, the creation of a state-run compensation scheme fitted with their conception of health care as an important provision by central government. In the United States, there was understandable reluctance to deny claimants the possibility of attaining damages through the court process, since there was less of a social security safety net to support individuals with ongoing ill health and disability.

Authors were critical of the tort system and its role in the compensation process. They described it as imprecise, since some undeserving claimants were successful, and many deserving cases were unsuccessful. In some non-UK contexts, they argued that the tort system was unfair, favouring those who could afford to pay for expensive lawyers and discriminating against the poor.

There were assertions of damaging effects on claimants, on their physical and mental health (e.g. Grant et al. 2014, Sterling et al. 2010), and on their incomes. The tort system could lead to distress for doctors and nurses, causing early exits from the profession, long-term sick leave (Robertson and Thomson 2014) and claims by doctors in the UK of a greater likelihood of practising defensive medicine (Bourne et al. 2015). There were examples of costs to the health system as a whole, particularly in the defensive practices of over-ordering tests and conservative treatments as clinicians sought to protect themselves against malpractice suits. Further, negative defensive medicine (e.g. restricting or denying care or treatment to patients considered too 'riskier' by clinicians) could contribute to inequalities in health systems.

The empirical research attempted to test out the effect of no-fault schemes and tort reform on these issues. This research alongside more theoretical contributions, enabled the development of propositions which explained the observed effects of no-fault schemes and tort reform when they were compared to the tort system. These explanations gave reasons for: the more precise targeting of compensation for intended beneficiaries (Davis et al. 2002); the impacts on physical and mental health outcomes (Cameron et al. 2008; Montgomery et al. 2015), and health system costs (Vandersteegan et al. 2015); the more equitable access to justice (Bismark et al. 2006a, 2006b) and health care (Dubay et al. 2001); the importance of procedural justice (Siegal et al. 2008); the possibilities of improved patient safety (Wallis 2013); and the limited information on medical error (Wallis 2015).

There was a lack of studies regarding the physical and mental health impacts of no-fault schemes where the claimants had suffered an injury as a result of medical treatment. The mental health detriment suffered by those experiencing injury through medical error may be greater than those injured in car accidents, since iatrogenic injury may represent a breakdown in trust not experienced by car accident victims.

Strengths and limitations

The process we adopted aimed to focus on the needs of policy makers as they considered different policy options, and allowed for iteration as researchers and policy makers considered the most relevant issues for exploration. Using this process, we developed our CMO configurations in consultation with the policy team at DH.

As in all realist reviews, we relied on snowballing techniques to identify relevant literature, picking up terms in papers as we read them in order to use them in further searches, as well as mining papers for citations and searching for papers that cited included studies. In this respect, the process of identifying the studies to include in the review is not entirely replicable. We only included studies that provided new explanations and discarded those that repeated explanations. These papers would be included if a more in-depth review was commissioned to test our CMO propositions.

Throughout the review, the team has engaged in discussions about the included papers in order to refine the CMOs and to check our understanding of the arguments, results and conclusions of the papers. Two researchers carried out data extraction on the included studies and met to discuss the clarification of the initial CMO, the structuring of the evidence and the contribution of each of the papers. In line with a realist approach (O'Campo et al. 2015), we have assessed the studies according to their relevance and the richness of their descriptions regarding the effects of no-fault schemes or tort reform on the lives of claimants and doctors. This was an appropriate approach in this review, as we were not using the papers to determine cause and effect, but to identify the range of possible mechanisms that might influence engagement in NFCSs. The papers are not directly comparable since some are empirical studies, some are policy reviews and one uses economic modelling. However, we did not include opinion pieces, commentaries or editorials, as we found the most useful studies to be those with some evidential basis.

Implications
This group of studies:

Can contribute to our understanding of how 'no-fault' compensation schemes can benefit key stakeholders, namely patients, health professionals and the health system as a whole. The range of benefits, discussed by the studies, include improved targeting of compensation to those most deserving of it, and speedier physical recovery after injury.

However, the complexity of the interactions between compensation processes, individual circumstances and the health systems in which the schemes are embedded, make it difficult to establish strong possible causal pathways, most notably regarding health outcomes.

The shape of the schemes will be highly influenced by the health system context, which, in turn, is affected by the prevailing political opinion about the role of the state in health care.

Part 1: Background, brief methods, findings and implications

1. Background

1.1 Description of the problem

At present in the UK, compensation for medical injuries can be sought through the tort system, where patients or their families attempt to claim compensation through litigation. Financial payouts may be made through out-of-court settlements or through the courts. No-fault compensation schemes (NFCSs) could provide an alternative, and perhaps more egalitarian method to redress claims resulting from medical injury (Farrell et al. 2010). In other countries, a range of birth and non-birth medical injury compensation schemes have been instituted (Cardoso et al. 2015; Farrell et al. 2010). Characteristics common to such schemes include: eligibility and threshold disability criteria, financial caps and/or limits to the extent and type of cover provided; differing levels of entitlements; levels of access to justice; restricted court access; and the existence of a comprehensive national social welfare/social insurance system (Farrell et al. 2010).

Currently, an administrative compensation scheme for birth trauma does not exist in the UK. However, several compensation schemes for other health issues are in place. Some of these may share circumstances with some similarity to those in which birth trauma occurs (i.e. occurring in early life), for example, vaccine-related injury, variant Creutzfeld-Jakob Disease (vCJD), thalidomide poisoning or contaminated blood transfusions, while others are less similar, such as traffic related injuries, workplace asbestos-related injury, violent crime.

The extent to which the context of compensation affects whether such schemes are taken up by affected families is not known; such factors include the wider socio-legal and health care system, the type of precipitating event and the characteristics of those who institute claims. It is argued that, in general, compensation schemes have the advantages of greater access to justice via financial reward, improved efficiency in time and costs, improved patient-provider relationships and reduced numbers of legal actions. However, these may come at a cost, including lower entitlements, a significant rate of application rejection, and a potential reduction in the quality of health professional care and institutional accountability (Farrell et al. 2010). This suggests that the uptake of NFCSs could be influenced by multiple social and individual factors.

1.2 UK policy context

The number and value of litigious claims for medical injury compensation lodged against the National Health Service (NHS) has been rising substantially in recent years (Thomas 2015). Maternity services comprise one of the areas of 'highest clinical negligence claims' in terms of both number of claims and costs reported to the NHS Litigation Authority (NHSLA) (2012 p.4). This may be due in part to the fact that injuries resulting from birth trauma can impact significantly on the morbidity of newborn infants (Lain et al. 2012, Perez et al. 2013). 'Between 2000 and 2009, over 5,000 claims were made totalling £3.1

billion' (NHSLA 2012 p.4). This represents less than 0.1% of all births in England during a similar period.

A review of the NHSLA, which manages litigation on behalf of the English NHS, noted that there was 'a need to rethink the approach to reducing the incidence and cost of claims to the NHS' (Thomas 2015 p.5). As the Chair wrote, 'the environment in which we operate means that the costs of litigation are placing a burden on NHS finances of a magnitude that was never imagined when the NHS LA was established [in 1995]' (NHS Litigation Authority 2015 p.4).

Aside from the large and increasing cost to the NHS, other disadvantages of the current compensation system include the time taken to resolve claims (Farrell et al. 2010), limited access to justice for the most vulnerable through the abolition of most legal aid (Dyer, 2013), the fact that a substantial proportion of money paid out goes to the legal profession rather than the victims, and the disproportionate, excessive and increasing claimant costs for lower-value claims (NHS Litigation Authority 2015).

Consideration of an NFCS is not novel: it was first considered in Scotland, but rejected, in 1978, when critics feared that it would encourage more claims and so increase costs (Dyer 2012). An administrative compensation scheme was also raised as a possibility in the *Making Amends* report (Department of Health 2003), which suggested that a no-fault compensation could be made available for babies who were severely neurologically impaired during birth, but was subsequently dropped. In 2011, the Parliamentary Select Committee on Health rejected similar proposals , citing costs and a concern that it would reduce the level of compensation for those most in need.

In Scotland, an expert group was convened in 2009 to consider the possibilities of a non-fault compensation for medical injury but not specifically related to birth. They recommended the adoption of a scheme based on the Swedish model (McClean, 2011); a consultation on their proposal was held in 2012, with the government's response published in 2014. Further consultation is also in progress on an avoidable harm scheme for lower value medical injury claims (Scottish Government 2014).

1.3 Review aims and approach

This rapid realist review builds on existing research activity which has primarily focused on identifying and describing existing fault and NFCSs in the international literature (e.g. Farrell et al. 2010). However, there is a lack of evidence analysing the individual and contextual factors contributing to the process of engaging with compensation schemes, an identification of the circumstances that could support uptake or an understanding of the pathway from contextual mechanisms to different types of outcomes.

The overall aim of this review is to fill that gap by developing a preliminary theoretical framework of the mechanisms entailed within the structure of a compensation scheme that could influence engagement in NFCSs or schemes that are equivalent in size and scale. This theoretical framework also aimed to describe the context and mechanisms that might lead to improvements in outcomes for affected patients. We sought to achieve these aims by seeking evidence to address the following research questions:

Review question 1: *What individual or contextual factors contribute to people's reasons and motivations for engaging in no-fault type compensation schemes after medical injury? (RQ1)*

Review question 2: *How are no-fault compensation schemes thought to improve outcomes for people with medical injuries? (RQ2)*

A realist review was chosen as an appropriate method as it is specifically designed for analysing information on varied and complex interventions implemented across more than one context and policy area and because a realist approach can be used to explore the suitability of interventions for particular circumstances or to refine interventions for different contexts (Rycroft-Malone et al. 2012). To fit with a time-restricted policy window, this review focused on answering these questions by conducting the first part of a realist review: identifying empirically and theoretically-based contextual, mechanisms and outcome (CMO) configurations. We did not test the effectiveness of each CMO configuration proposed (second part of a realist review). The review follows the publication standards suggested by the Realist and Meta-Narrative Evidence Syntheses: Evolving Standards (RAMESES) project (Wong et al., 2013; see Appendix 1) and indicates where modifications were made to fit with the short policy time-frame (December 2015 to April 2016).

2. Brief methods

This chapter provides a brief overview of the methods used to conduct the review in order to facilitate readability for those more concerned with the overview of the context, mechanisms and outcome configurations and the text provided to justify them. A fuller description of the methods is provided in Part II of this report.

2.1 Type of review and user involvement

As stated, to fit within this time-frame this review focused solely on the first part of a realist review: identifying empirically and theoretically-based contextual, mechanism and outcome (CMO) configurations. This review was conducted iteratively through: 1) initial searching and definition of the scope of the review; 2) further searching and iterative screening of primary studies; 3) assessment of relevance and data extraction of studies; and 4) developing an evidence-informed preliminary theoretical framework in the form of CMO configurations (Rycroft-Malone et al. 2012; Saul et al. 2013). We met regularly with the DH policy leads throughout the review process to ensure that the review was closely aligned with their needs and emerging policy requirements.

2.2 Conceptual framework and preliminary CMO framework

The initial conceptual framework guiding the review was based on the key features of NFCSs for medical injury identified in the review by Farrell et al. (2010 pp.8-9) and were expressed in the protocol:

It is argued that, in general, compensation schemes have the advantages of greater access to justice, improved efficiency in time and costs, as well as in patient-provider relationships, and reduced legal actions; however these may come at a cost, including lower entitlements, a significant rate of application rejection, and a potential reduction in the quality of health professional care and institutional accountability (Farrell et al. 2010)

This statement formed the starting point for the investigation into the compensation schemes. During the protocol development, we began by reading some key studies to develop initial hypothetical configurations between contexts, mechanisms and outcomes. We defined and understood context to consist of the compensation schemes for injuries occurring during birth and early childhood or in other medical injuries, as they are played out in Western welfare states. Mechanisms included the factors contributing to claimant motivation to engage with compensation schemes as well as aspects of the design of the schemes that might trigger greater engagement.

We developed some initial CMOs relating to claimant experience by looking at reviews that discussed compensation policies. These CMOs became the initial conceptual framework for the study, and we asked the policy team at the DH to prioritise those they would like to investigate further. This discussion informed the later searches, where we used the data extraction and analysis stage to refine, confirm or refute these configurations. After these initial conversations, the team indicated an interest in outcomes for clinicians relating to clinical practice, patient safety and clinician well-being. We went through the same process of developing crude CMOs to prioritise and narrow our later searches. The stages

of the CMO development for claimants and clinicians are documented in more detail in Part II, the technical report.

2.3 Identification and selection of papers to inform the CMO configurations

To be eligible for inclusion in this review, papers needed to focus on a no-fault type compensation scheme or tort reform[3], relevant to potentially iatrogenic injuries in children occurring at birth or in the early years (under five), or which have two of the three characteristics similar to birth trauma compensation schemes: high-value claims; high long-term costs; highly emotive. They needed to examine contextual factors influencing the delivery mechanisms of schemes and/or contribute to our understanding of CMOs, i.e., contain information about the effects of compensation schemes on patient and clinical outcomes. Initially we looked for papers published within the past ten years. This timescale identified literature most relevant to the UK context since the introduction of both the Making Amends report and the NHS Redress Act 2006, both of which dealt with medical liability reform (Department of Health 2003; UK Parliament 2006). However, we included papers outside that timeframe when they contained pertinent information, such as Dubay et al. (2001).

2.4 Data extraction and relevance appraisal

Descriptive characteristics were extracted from the studies, specifically, what type of NFCS and country the study investigated, and whether the focus of injury was medically caused or not. Further empirical and descriptive information from the studies was extracted, drawing on the initial conceptual framework with newly identified concepts added to this framework as they appeared in the literature (see Appendix 2 for the coding tool). We also developed criteria specifically to assess the relevance of papers to answer the review questions. First, we made an assessment of whether the paper aimed to investigate, explore or describe the implementation or introduction of NFCS for birth injury, medical injury or other types of injuries. Second, we assessed whether the paper provided information or empirical evidence on uptake or on any one of the CMOs, e.g., whether there was sufficient explanation of why compensation schemes, or their different mechanisms, led to a particular outcome. Based on answers to these questions, an overall judgement of high, medium or low relevance was made. Overall, evidence was considered to be of low relevance when the focus was not medically related or when speculations from the authors were unsupported by empirical evidence from the study they were reporting on.

2.5 Developing the CMO framework and appraisal of relevance

Empirical and descriptive data from studies on how different factors appear to affect uptake and engagement in NFCSs and the manner in which they operate (mechanisms) were combined from individual studies (Oliver et al. 2008; Thomas et al. 2012). Our initial work focused on refining the CMOs so that they were as practically specific as possible. This was made possible through reflective discussion between two reviewers (KD and KH) to consider the data extracted, whether they supported the CMOs and where refinements needed to be made. The analysis of the studies against these CMOs aimed to clarify and

[3] *Tort reform refers to a set of proposed changes in the legal justice system focusing on the extent to which individuals can claim for damages as a result of medical or non-medical injuries*

substantiate our thinking about why we had structured the CMOs in this way. Thus the syntheses justified the configurations as they are presented in the report. At the study selection stage, reviewers discussed in detail a sub-set of papers potentially relevant to informing the CMO framework in terms of their richness, depth and level of empiricism. All papers were checked by a second reviewer to confirm they met the inclusion criteria for relevance.

3. Findings

As stated, our review aimed to develop a preliminary framework of the mechanisms influencing engagement in NFCSs. Using a realist approach, we sought to understand the connections through which different components of NFCSs, which operate under certain social and political systems, are thought to influence patient and clinician outcomes. This section outlines our context, mechanism and outcomes (CMO) framework based on our review of the papers. It is organised according to the four main outcome categories identified in the literature and prioritised as of interest to policy (Section 3.3).

The text in bold, under each outcome, is the CMO configuration, and is written in the form of a proposition or a hypothesis. This configuration was developed from the literature, acting as a summary and a distillation of the text following it. In turn, the text acted as a justification for the wording of the proposition. This enabled us to be transparent in the presentation of the arguments for compensation schemes found in the literature. We searched for papers that challenged the propositions, and where we found them, we included them in the text. We assessed these papers for relevance, thus, the review makes no claims about causal links, as this was not its aim (and might be highly challenging in such complex and diverse contexts).

Further, it is important to reiterate that very few papers related directly to compensation for birth injury. However, we have included those papers that describe mechanisms relating to medical injury, worker compensation and road accident insurance where the notion of no-fault affected outcomes. We argue that looking at the broadest range of circumstances enables a fuller picture of the effects of no-fault schemes.

3.1 Evidence informing the CMO framework

We found few papers providing qualitative evidence to directly answer our research question about the contextual factors that might influence and affect the uptake of NFCSs for patients affected by medical injury (RQ1). However, our exploration of the mechanisms associated with no-fault schemes (RQ2) gives us some information about the possible motivations of patients and clinicians to engage with such schemes, providing some understanding about question one. To answer the second review question, relating to the proposed mechanisms in NFCSs thought to lead to patient and clinical practice outcomes, we draw from 44 papers, the majority of which are empirical studies (n=33) or policy reviews drawing on empirical data (N=11). The papers provided evidence on a range of social contexts in which fault-based and NFCSs operated (Table 3.1). Further details of the characteristics of papers can be found in Appendix 3.

3.2 Key features of no-fault compensation schemes

The components entailed in NFCSs for medical injuries vary across high-income countries. The main differences focus on the definition of eligibility criteria to determine fault and how schemes are funded and organised. An overview of the different approaches to compensating people who have experienced a medical injury is provided in the table below.

Table 3.1: Overview of medical no-fault compensation schemes*

Key components	United State† (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 of employable age
Continued access to courts	No	Yes	Yes	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 non-economic damages	Economic and non-economic damages	Economic damages

* Schemes operating in Australia are omitted as they report non-medical compensation schemes
†Drawing on two no-fault birth injury schemes available in Florida and Virginia
†† Nordic countries include Sweden, Denmark, Norway, Finland and Iceland, with specific details of schemes varying across countries.

NFCSs specifically for neurological birth injury are in place in two US states: Florida and Virginia; other countries operate NFCSs for a range of medical treatments. The US-based birth injury schemes insist that, to be eligible, the birth injury has to be the result of the birth process, and they exclude injuries caused by genetic or congenital abnormality. France has implemented two systems: a no-fault standard for serious and unforeseen medical injuries; and a fault standard, where access to the courts remains for those putting in an initial claim.

The Nordic countries operate an 'avoidability' standard, compensating patients who have experienced injuries that could have been avoided under optimum conditions, for example, where the injury would not have occurred under the care of the best health practitioner/system. Here it is referred to as the 'experienced specialist' rule. An administrative scheme is in place to provide patients with a non-litigious route to compensation. Claimants have the right to appeal a decision made by schemes. They can

also appeal to the courts if dissatisfied with the outcome of that appeals process and/or directly pursue a tort-based claim.

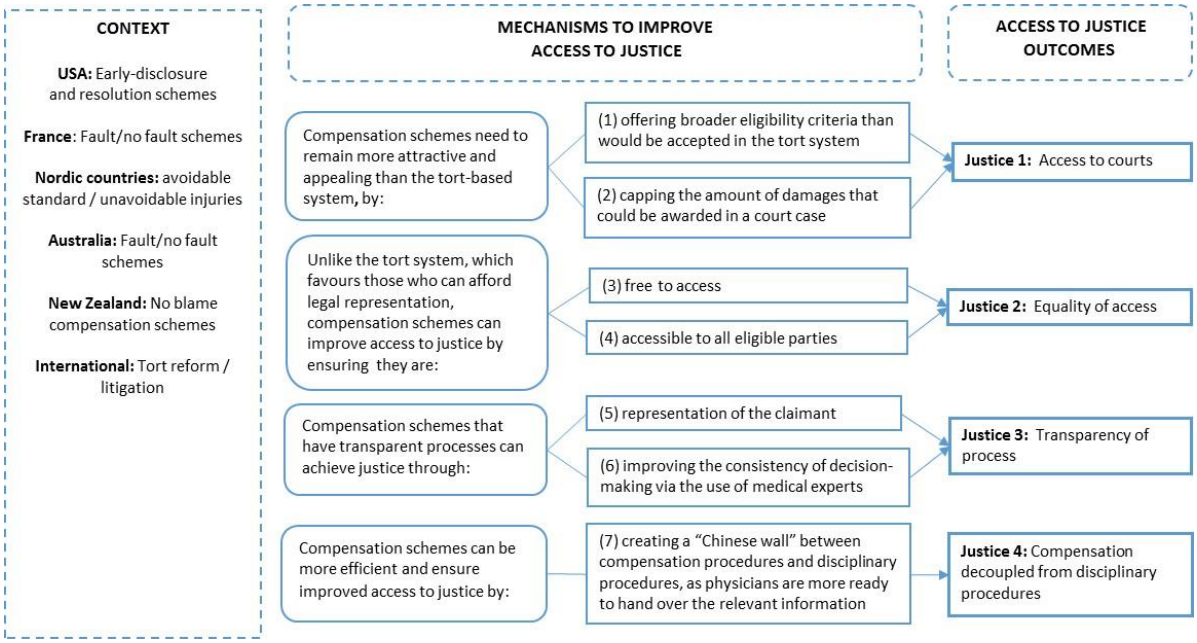
New Zealand has put in place the broadest eligibility criteria, with a no-fault standard applicable to any unexpected treatment injury. The only scheme to operate without a financial cap is in France and all but the New Zealand schemes aim to cover both economic and non-economic costs.

3.3 Context, mechanisms and outcome configurations: preliminary theoretical frameworks

3.3.1 Access to justice

Four distinct 'access to justice' outcomes were identified in the literature. These outcomes focused on: the extent to which schemes are more appealing than accessing the courts; ensuring equality of access to compensation schemes; processes related to the transparency of schemes; and the importance of ensuring that compensation schemes are decoupled from disciplinary procedures (see Figure 3.1). The 14 papers providing information on these outcomes represent six policy contexts cited in this review (the USA, France, the Nordic countries, the Netherlands, Australia and New Zealand).

Figure 3.1: Access to justice



3.3.1.1 Justice 1: Access to courts

To make compensation schemes attractive to claimants, they must offer payments comparable to damages awarded through litigation and include broader eligibility criteria, to ensure that schemes remain more appealing than the tort-based system.

The schemes differ in the extent to which claimants can access the court system. In Scandinavia and New Zealand, claimants may appeal the decision of ineligibility made by claim assessors and, if unsuccessful at this first appeal stage, can take their case to the courts (Kachalia et al. 2008). In Virginia and Florida, claimants are restricted in their access to court by the sign-up of the provider to the compensation scheme. If a provider

subscribes to the scheme, then the claimant does not have access to court and must claim through the scheme. If the provider is not part of the scheme, then they can pursue their claim through the courts. In Florida, where there is extensive sign-up to the compensation scheme, there are many disputes about the notice about compensation provision given to patients as they take up care, since this forecloses choice about litigation. In Virginia, where fewer providers have signed up, there are more choices for patients regarding provision, either with those who are covered or those who are not (Siegal et al. 2008). In France, the compensation scheme only covers those with severe injuries incurred as a medical mishap. If fault can be established, then the claimant must pursue this in court (Barbot et al. 2014).

Broader eligibility

Only France insists on establishing the personal liability of providers. If this is achieved, then the claimant has access to the courts. All the other schemes do not seek to establish the personal negligence or liability of the provider.

In Virginia and Florida, the claimant has to establish causation as a result of the birth process. This can be difficult in cases of cerebral palsy, so the compensation process usually gives claimants the benefit of the doubt. In this way, the compensation process broadens the eligibility criteria by accepting cases that would not be accepted by the courts (Siegal et al. 2008). This makes the administrative compensation process more attractive to claimants in a system where there is greater expectation of a litigation process to resolve disputes.

Fewer claims to the compensation scheme are made in France, attributable to the higher eligibility threshold that needs to be met for acceptance into its scheme. Barbot et al. (2014) found that access to courts remains an appealing option to claimants because of this 'relatively high level of injury gravity required' to access the NFCS and 'the maintenance of a fault standard' which may contribute to providers being reluctant to facilitate claims' (Barbot et al. 2014 p.241).

Kachalia et al. (2008) provide an overview of the criteria for compensability of medical injury in three countries (Denmark, Sweden, New Zealand), in order to compare them to the tort system in the US. They discuss the avoidability criterion in Scandinavia as an example of the administrative schemes broadening out the eligibility criteria. The avoidability standard has a lower threshold than the negligence standard, commonly used by the tort system, so a greater number of claims can be made in the administrative scheme than would be accepted in court. It introduces the idea of judging provision against the best possible care available at the time of the incident, in terms of specialist physicians, treatment and drug choice. In Denmark, they adjudicate more strictly than in Sweden, but to balance this, have added an endurability criterion which is compensation for catastrophic injuries. These injuries result in disabilities of such severity that exceed a level which patients could be reasonably expected to endure, whether the injury is avoidable or not. This is more widely applied than the one allowed in Sweden for hospital-acquired infections (Kachalia et al. 2008).

New Zealand has the broadest eligibility criteria, with compensation claimable for any injury caused by medical treatment (since 2005) and is perhaps the truest 'no-fault' system. It is limited by the requirement that the injury is caused by active treatment, so

it does not cover injury caused by omission, such as late diagnosis. It also covers loss of wages and is only open to those of employable age.

Capping damages
In compensation processes, damages can cover both economic losses and non-economic costs, usually referred to as 'pain and suffering'. New Zealand limits payments to economic costs, most importantly lost wages as a result of the injury. It does not pay non-economic damages, but schemes in other countries do make a one-off payment for this (Kachalia et al. 2008).

Aside from France, the majority of NFCSs operate a financial cap. Figures for average payouts in European countries are reported in Barbot et al. (2008 p.241), with the highest in France (US$ 102,000) compared to other countries, such New Zealand (US$ 12,500), Sweden (US$ 22,000) or Denmark (US$ 30,000).

In Florida and Virginia, a total cap on damages awarded via the courts was introduced to encourage usage of birth injury compensation programmes. The Virginia birth injury programme first adopted the cap in 1992, ensuring that the amount payable was similar to what would be available through their programme. However, Florida did not put a cap in place until 2003, after finding that many attorneys were encouraging claimants to go through the courts, believing that they would be awarded higher damages (Siegal et al. 2008 p.496). The caps in the US are set at a much higher amount (US$ 750,000), since the universal health care available in the other countries is expected to provide an ongoing safety net (Kachalia et al. 2008) not available in the US.

3.3.1.2 Justice 2: Equality of access

NFCSs that are free to access improve justice outcomes in that they are accessible to all eligible parties, unlike the tort system, which favours those who can afford legal representation.

All the 'no-fault' schemes are free to eligible parties. In Scandinavia, claimants can access the system without physician support, but in New Zealand, a doctor makes the claim on behalf of the claimant (Kachalia et al. 2008). In the US schemes, some claimants choose to use legal representation to make claims, although it is not necessary, which inevitably increases the expense to the claimant (Siegal et al. 2008).

Davis et al. (2002) and Bismark et al. (2006a) conducted empirical studies to examine the level of claiming in the New Zealand scheme, and Armstrong and Tess (2008) later used the Davis study data in their review of no-fault schemes to make a comparison with the fault system. Davis et al. (2002) used data from 1995 hospital admissions to decide which injuries would be compensable, and then looked at ACC (Accident Compensation Corporation) records to find out if claims had been made and whether they were successful. They found that roughly 1 in 30 potentially compensable claims were made, but of those claims made, 60% succeeded. They concluded that the scheme was well-targeted, in that the claims made were compensable. However, there was pervasive under-claiming. Likewise, Bismark et al. (2006a) found that the vast majority of eligible patients (97%) did not claim. The risk factors for not claiming are discussed below.

Armstrong and Tess (2008) compared success rates in the fault system in the USA – only 8% of those injured in the medical system received any compensation – with those in the no-fault system, and concluded that the number of claimants was low in both circumstances. In their discussion, Bismark et al. (2006a) mentioned that the proportion claiming was close to that estimated in tort systems in New York in the late 1980s and Utah and Colorado in the late 1990s. So we can conclude that under-claiming is common to both the administrative compensation schemes and the tort system.

However, the figures from Davis et al. (2002) and Bismark et al. (2006a) are out of date, since the New Zealand scheme changed in 2005 to remove the notion of 'fault' and to move to the eligibility criterion of 'treatment injury'. This has considerably broadened the scope for compensation, and Bismark et al. (2006a) conclude that the claim rate will climb as a result.

Patterns of claiming

Some papers have described the profile of claimants and non-claimants in order to understand patterns of inequality that may exist. These studies have considered the New Zealand scheme (Bismark et al. 2006a; Davis et al. 2002; Sobrun Maharaj et al. 2010), the Finnish scheme (Jarvelin et al. 2012) and the schemes in Florida and Virginia (Siegal et al. 2008). Bismark et al. (2006a) and Siegal et al. (2008) considered aspects of the schemes themselves that may create inequalities.

Individual characteristics: claimants

Claimants were generally people of working age (Bismark et al. 2006a; Jarvelin et al. 2012), female (Davis et al. 2002), those with co-morbidity (Jarvelin et al. 2012) and those who suffered permanent disability (Bismark et al. 2006a). In their study of patients undergoing knee and hip operations, Jarvelin et al. (2012) also found that the type of prosthesis predicted claims. Further, hospitals with low volumes of this kind of procedure were more likely to attract claims.

The economic advantages to those of working age were apparent in the New Zealand scheme, as only economic damages are paid, usually loss of wages, without a one-off payment for pain and suffering as in other schemes, such as in Scandinavia and the US. Additionally, their need may be greater, as this group often must provide for dependants (Bismark et al. 2006a).

Davis et al. (2002) explained that the finding that higher numbers of women claim, was a result of surgical procedures in obstetrics and gynaecology. They suggested that causation was easier to establish in the case of surgery than in more general hospital care.

The explanation for higher rates of claiming amongst those with co-morbidity pointed to patients who were well acquainted with the health system and often with a level of dissatisfaction with their care (Jarvelin et al. 2012). However, this finding was not statistically significant.

The finding concerning permanent disability was accounted for by high need leading to a clear advantage to claim, and the claims being usually compensable (Bismark et al. 2006a).

Individual characteristics: non-claimants

The missing populations from the claiming group were older people (> 65 years) (Bismark et al. 2006a; Jarvelin et al. 2012); ethnic minorities (Bismark et al. 2006b; Sobrun-Maharaj et al. 2010); the socially deprived (Bismark et al. 2006b); and those suffering temporary disability or the death of a family member (Bismark et al. 2006b).

For older people, there appeared to be few benefits to claiming in New Zealand, as payment was calculated on loss of earnings. Medical costs are paid for in New Zealand without claiming, so reducing the need to claim for this group. Conversely, there were much higher claims in dental cases for this group. These injuries were likely to involve out-of-pocket expenses, as dental care is not covered by the state's social security system (Bismark et al. 2006b). Likewise, Jarvelin et al. (2012) concluded that there were much lower economic losses for this group, so they were less likely to claim, but they also thought that older people might be more accepting of poorer outcomes in later life.

Sobrun-Maharaj et al. (2010) investigated the low rate of claiming for Asian communities in New Zealand through interviews and focus groups. They found barriers pertaining to: language, both in application forms and the lack of interpreters needed to deal with assessors during the process; fears about Western medicine amongst elders; tensions for assessors to provide culturally appropriate services, as against providing the same service for all; and a belief that claiming jeopardised future employment.

Bismark et al. (2006b) found that Maori and Pacific communities were less likely to claim. They suffer from social deprivation in many areas, such as education, justice and health, and with other socially deprived communities, were also disadvantaged regarding compensation for medical injuries. Bismark et al. (2006b) concluded that the 'no-fault' system exhibited the same effects as tort for these social groups.

The final characteristic of interest was the type of injury. In New Zealand, those with temporary disability, or families of those that had died, did not tend to claim. Bismark et al. (2006) concluded that patients and their families did not see enough economic advantage in doing so.

In their conclusion, Bismark et al. (2006b) commented that these patterns of claiming were common across all schemes, whether in New Zealand or Scandinavia.

Scheme characteristics

There was some discussion as to whether the schemes themselves might present barriers to claiming (Bismark et al. 2006a; Siegal et al. 2008).

Bismark et al. (2006a) argued that the idea of 'fault' may discourage doctors from disclosing an accident and injury, therefore patients may not realise that they have injuries that are compensable; this would contribute to under-claiming. It was thought that the changes to the New Zealand scheme, which took away the notion of fault and moved to the eligibility criterion of 'treatment injury', would overcome problems with disclosure.

In discussing the schemes in Florida and Virginia, Siegal et al. (2008) pointed to the burden of proving causation placed on the claimants as a problem. The need to hire lawyers to do this mimics the tort system. Inequality became apparent, as those who could afford a lawyer succeeded in achieving higher damages.

In Florida and Virginia there is differential access to the schemes, as they are controlled by sign-up of providing physicians and hospitals, with not all physicians and health care providers choosing to participate. Some observers thought that this might disadvantage poorer people allocated to physicians and hospitals not participating in schemes, who may have limited choices regarding legal representation if subsequently required. Mandatory sign-up for all physicians might make the system more equal (Siegal et al. 2008).

3.3.1.3 Justice 3: Transparency of process

Transparency of process achieves justice through the representation of the claimant, and mechanisms that improve the consistency of decision making through the use of medical experts and the consideration of precedents.

Considering the two types of schemes under comparison, the mainly administrative schemes from Scandinavia and New Zealand, and those with a greater influence from the tort system, it is apparent that they rely on different mechanisms to achieve trustworthiness. The administrative schemes place greater emphasis on medical expertise and referral to previous decisions to ensure consistency of decisions (Kachalia et al. 2008), whilst the tort-influenced systems allow more opportunities for medical and legal representation (Barbot et al. 2014; Siegal et al. 2008).

Representation

There are various ways a victim might be represented in compensation processes. Most commonly representation is carried out by lawyers, but claimant advocacy is also taken up by patient groups in France, or through political appointees in the Virginia scheme.

The schemes in Virginia and Florida are closely tied to the legal system, as claimants will often use lawyers to file claims and to represent them at hearings (Siegal et al. 2008). In Florida, they also use lawyers to argue that they are not bound by the compensation scheme. In Virginia, the appeals process is carried out by political appointees, rather than medical or legal experts. In France, patient groups are represented on decision-making committees in line with the notion of solidarity at the heart of their scheme (Barbot et al. 2014). In Scandinavia and New Zealand, claimants have the right to be represented by patient advocates in the appeals process, although in New Zealand, claimants rarely take this up (Kachalia et al. 2008).

Representation by lawyers may increase trust in the system by clarifying the medical issues for the client (Murtagh et al. 2012; Siegal et al. 2008) and acting as an ally against the state and the medical establishment. Murtagh et al. (2012) found that respondents were more likely to consult lawyers if offered a generous compensation payment. They commented that this might reflect distrust in the medical establishment and a desire to understand whether the offer was fair. The respondents may also regard the offer as part of a risk management strategy, rather than an outcome of professional ethics. Lawyers in these circumstances may prove helpful in facilitating an early settlement if they can confirm that the offer was reasonable (Murtagh et al. 2012).

Similarly, road traffic accident claimants were more satisfied with their interaction with lawyers than with insurance companies (Elbers et al. 2013), possibly because they were considered allies. Elbers et al. found that procedural fairness, e.g. increasing the

opportunities for claimants to participate actively in the compensation process by expressing their views and feelings, improved patients' quality of life.

However, observers in Siegal et al. (2008) found significant problems with the involvement of legal representation. They thought that the more adversarial legal process slowed up the system of decision making and soured relations between the claimant and the compensation authorities. This made care more difficult to deliver in a timely and acceptable way. They also pointed to inconsistencies in decision making by political appointees, due to their lack of medical or legal training.

Consistency of decision making

Given the difficulties of establishing the causality of medical injuries in the context of contested and evolving medical science (Siegal et al. 2008), the importance of retaining medical expertise to advise in the compensation process was acknowledged in all of the papers. However, medical experts did not make decisions but were called upon by assessors for their opinions about difficult cases (Barbot et al. 2014; Kachalia et al. 2008; Siegal et al. 2008). In Scandinavia and New Zealand, experienced assessors with clinical and legal expertise gather material from families and experts to inform their decisions about eligibility and level of compensation. They then write to the claimant to inform them of their decision (Kachalia et al. 2008). Consistency of decision making is maintained through the specialisation of the reviewer in areas of medical injury, reliance on a pool of medical experts retained by the company for opinions about difficult cases, and referral by the reviewer to previous cases which had been catalogued by the compensation authorities (Kachalia et al. 2008).

In Florida and Virginia, medical experts review all claims by examining the child and relevant medical records, but the final decisions are made by a judge in Florida or a commissioner in Virginia. In France, claimants have access to free medical expertise only after their case has been accepted as compensable. There was some variation as to how the boundaries of admissibility were defined in different regional jurisdictions in the French scheme, which affected access to medical expertise (Barbot et al. 2014).

In their evaluation of the schemes in Florida and Virginia, Siegal et al. (2008) suggested that training for the medical experts to support their understanding of legal terms and the creation of guidelines to aid decision making would improve consistency. They considered that consulting previous decisions made by the compensation authorities and greater exchange of information about decisions between experts would also improve consistency.

The advantages of attending to consistency was a more transparent and fair decision-making process, which led to a more efficient system (Siegal et al. 2008). There was less likelihood of challenge through the appeals process if claimants understood the reasons for their rejection, and decisions by the authorities were more likely to be upheld. Establishing trust in the system also enabled decisions to be made at assessor level, as in Scandinavia and New Zealand, rather than requiring a two-tier system of hearings (Siegal et al. 2008).

Commentators on the Scandinavian schemes thought that the 'avoidability' criterion was a more efficient standard to apply, since deciding what could have been done in the best

hands was regarded as simpler than judging whether a provider's action fell below the customary standard of care (Kachalia et al. 2008).

There were some disadvantages identified by observers in the Siegal et al. (2008) study, particularly concerning the medical experts. There were some concerns about conflicts of interest: given the small community of obstetrician-gynaecologists it was conceivable that experts would know personally the provider in any given case, potentially jeopardising their impartiality. Others were of the view that experts in the programme should be barred from providing expertise in malpractice litigation, since they might be swayed by the possibility of monetary gain as an expert in a court case.

The main concern of Siegal et al. (2008) was the lack of institutional memory in Florida and Virginia, due to the narrow range of experts and the lack of cataloguing of previous cases to enable referral to precedents. This is less a disadvantage of systems to improve consistency, but a recognition of the efforts needed to create and maintain them.

3.3.1.4 Justice 4: Compensation decoupled from disciplinary procedures

Creating a 'Chinese wall'[4] 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.

The compensation schemes in Scandinavia and New Zealand operate parallel systems of compensation and disciplinary procedures where the compensation system does not report to the authorities on individual doctors for disciplinary reasons (Mello et al. 2011). In New Zealand, this is an important mechanism, since claimants need to obtain support from doctors to make a claim. The fear of reputational and career repercussions for physicians was put forward as one reason for the low rate of compensation claims for medical injury in the previous version of the New Zealand scheme, since many people did not realise that they had a compensable claim, as providers were not disclosing iatrogenic injuries (Bismark et al. 2006a). The reforms in 2005 were designed in part to overcome this block to disclosure.

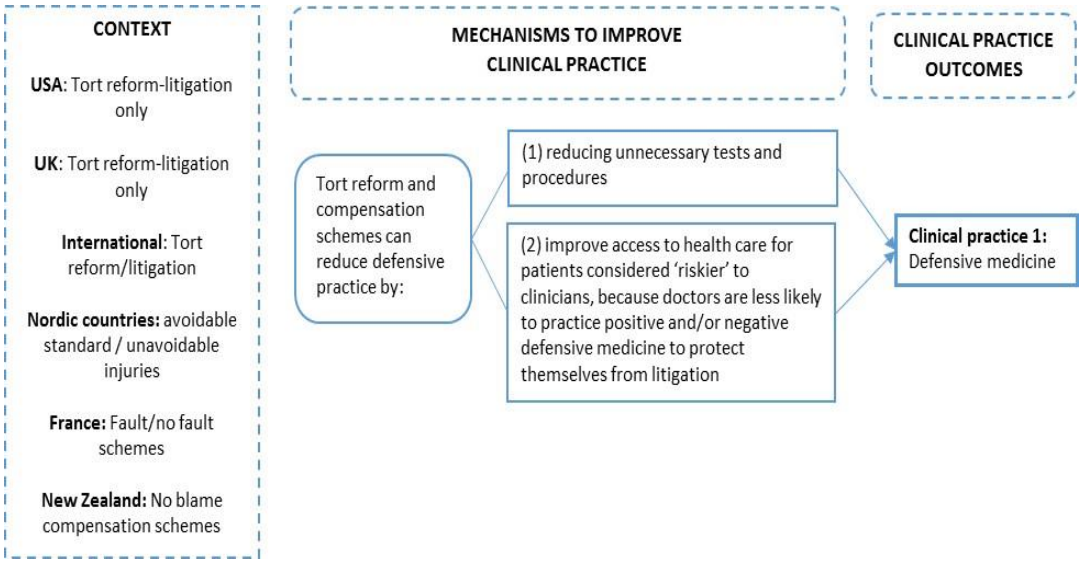
Doctors have responded to the reforms by assisting patients to claim and by providing information in a more timely way. In New Zealand, since the 2005 reforms, this has shortened the time to decision from 5 months to 13 days (Wallis 2013). Malcolm and Barnett (2007) attributed the greater readiness to disclose and the improved communication with patients by hospitals in New Zealand to the compensation schemes and the parallel complaints procedures. Wallis (2013) charted the decline in disciplinary procedures as a result of the 'Chinese wall' between the compensation process and the complaints system, which suggests that it affects accountability and also deterrence. These concerns will be discussed further under clinical outcomes and the theme of patient safety.

[4] A barrier that separates two or more groups, usually as a means of restricting the flow of information

3.3.2 Clinical practice

This section explores the mechanisms under which tort reform and no-fault compensations schemes are thought to lead to improvement in clinical practice outcomes (see Figure 3.2). Of the 14 papers contributing to an understanding of the effect of tort reforms on clinical practice, the majority draw on the medical-legal context in the USA (n=9). Further studies also add to our theoretical understanding by drawing on wider international contexts of compensation schemes and tort reform (n=5).

Figure 3.2: Clinical practice outcomes



3.3.2.1 Clinical practice 1: Defensive medicine

Tort reform and NFCSs reduce unnecessary tests and procedures and improve access to health care for patients considered *'riskier' by clinicians* because doctors are less likely to practise positive and/or negative defensive medicine to protect themselves from litigation.

The effect of malpractice pressure on physician behaviour is referred to as defensive medicine. This arises as doctors attempt to protect themselves against potential litigation by over-cautious ordering of tests and conservative treatment, i.e. positive defensive medicine, or by restricting or denying care or treatment to patients considered as 'riskier' by clinicians, either because of the seriousness of their illness (e.g. Konety et al. 2005) or because of socio-economic determinants (e.g. Dubay et al. 2001), i.e. negative defensive medicine. The costs of defensive medicine to the health system far outweigh the damages awarded in malpractice litigation, given the extent of under-claiming for medical injury, so it has been a topic of great interest to international policy makers (Kessler n.d.). Researchers have also examined defensive medicine's effect on the practices of doctors, access to care and outcomes.

The majority of papers discussing defensive medicine report on studies conducted in the USA, where the debate about the effectiveness of tort reforms has focused on whether defensive medicine exists sufficiently to warrant the restrictions placed on jurors when awarding damages (Kessler n.d.). Much of the debate centres on obstetric practice, as this

is a highly litigious area, which makes these papers very relevant to this review (Cheng et al. 2014; Dubay et al. 2001; Jena et al. 2015; Sakala et al. 2013; Sartwalle and Johnstone 2014; Shurtz 2013; Xu et al. 2013, Yang et al. 2009, 2012). However, the context of insurance premiums, reimbursement practices and the restricted access to care in the US system makes some of these findings less relevant to the UK context. One paper specifically examined OECD no-fault schemes in order to establish the extent of defensive medicine in countries with NFCSs, but did not focus on birth trauma (Vandersteegen et al. 2015).

Tort reforms in the US began with restrictions on non-economic damages enacted in California in 1975 to lower insurance premiums for physicians and halt their exodus from the profession and to other jurisdictions with less malpractice pressure (Kessler n.d.). Other American states have followed, with similar limitations on damages, including reducing payments for medical expenses so that plaintiffs are not personally reimbursed for costs already borne by their insurance company, known as the collateral source offset rule, and limiting the period during which plaintiffs can file a suit. These measures have reduced claims and awards and alleviating malpractice pressure in these states (Hugman 2007; Kessler n.d.).

International literature suggested that strong incentives may exist for doctors to practice defensive medicine. They do not bear the costs of the extra tests that they are free to order, but they do bear the personal costs of reputation loss from lawsuits, even if they do not pay damages to the plaintiff personally. These damages are paid by the NHS in the UK or the insurance company in the US (Keren-Paz 2010, Kessler n.d.). The ordering of tests may be tempered by state-administered systems, such as Medicaid, which have less generous reimbursement terms, but restrictions on payment may then affect whether doctors offer care to patients covered by these schemes (Dubay et al. 2001). Reputation loss will affect future career opportunities and financial losses in the US, where patients choose their doctors. It also results in mental distress and loss of confidence, as Robertson and Thomson (2014, 2016) found in interviews with midwives involved in court cases in the UK.

Establishing the presence of defensive medicine is usually carried out by examining the effects on health budgets after the pressure of malpractice liability is lessened through the introduction of tort reform. In their review of the best evidence for the relationship between tort reform and Caesarean section rates (a common positive defensive medicine strategy in obstetrics), Sakala et al. (2013) found that there was no association between liability pressure and avoidance behaviour. Likewise, others have found no statistically or economically significant effects of malpractice pressure on the cost or quality of health care more broadly (Baicker and Chandra 2005; Baicker et al. 2007; Hellinger and Encinosa 2006), which would suggest that defensive medicine is not practised enough to be affected by the lessening of malpractice pressure.

However, in his economic modelling of the effects of negative defensive medicine, Montanera (2016) points out that these studies do not take enough notice of the effects of reducing malpractice pressure on enabling greater access to health care for riskier groups. His conclusions were that for low-risk populations, such as those from wealthier backgrounds and with an illness or condition in a medical speciality with low litigation

risk, tort reform would reduce spending on unnecessary procedures and so save money for the health system. However, for a high-risk population, such as those from poorer backgrounds and with an illness or condition served by a medical speciality of high litigation risk, costs to the health system would rise as these people gained greater access to health care. Thus, tort reform could not deliver both savings to the health system and improved quality of care, if the population was homogeneous. In the case of positive defensive medicine, the health system would save money from tort reform if the population was wealthy or had illnesses and conditions served by a medical speciality of low litigation risk. In the case of negative defensive medicine, costs would rise as access improved because poorer and riskier patients would have access to medical care, which had been denied previously. It might be able to deliver both if the population was heterogeneous, but there would be a tendency towards savings or quality of care depending on the make-up of the population. Therefore, he did not support the conclusion from the empirical studies showing no statistical effects that doctors did not practise defensive medicine, but rather explained that these studies were conducted with a heterogeneous population.

Vandersteegen et al. (2015) examined the differences in health care spending between countries with NFCSs which decoupled compensation from disciplinary procedures, such as those in New Zealand, Sweden, Norway, Denmark, Finland and Iceland, and those that did not, such as those in France and Belgium. They argued that compensation schemes that protected the reputation of the doctors would result in less over-cautious practice. They found that those no-fault systems with decoupling had lower spending on health care (−0.06%), whilst those without had higher spending (+0.06) when compared to health care spending in 34 OECD countries. Figures for health care spending came from a literature review of studies comparing expenditures in OECD countries. In the final estimation of expenditures, GDP per capita, the age profile of the population, the number of physicians per 1,000 citizens, the proportion of publicly funded health care as a measure of the political environment and a test to take account of macro-economic effects and the rate of technological change were controlled for. The best results (−0.11%) were found for those compensation systems that were privately financed through pooled insurance schemes.

Positive defensive medicine can change practices in various ways, such as increasing referrals to specialists (Xu et al. 2013) increasing diagnostic tests and using tests of spurious medical value (Sartwalle and Johnstone 2014). Many studies examine the use of Caesarean section as a positive defensive strategy, since clinicians believe that it makes the birth process easier to control (Cheng et al. 2014; Jena et al. 2015; Shurtz 2013; Yang et al. 2009) although this finding has yet to be fully empirically tested. In non-UK contexts, experience of litigation and medical error made doctors more likely to recommend Caesareans (Cheng et al. 2014, Shurtz 2013). Jena et al. (2015) found that greater spending on resources and higher Caesarean rates predicted lower rates of malpractice claims. Sartwalle and Johnstone (2014) questioned the use of electronic foetal heart monitoring as a tool to diagnose cerebral palsy in unborn babies, as changes in heart rate picked up by the monitor can trigger Caesareans. Although clinical trials have consistently shown that electronic foetal monitoring produces false positive results in 99.8% of cases, lack of monitoring is taken as negligent behaviour in most lawsuits. They

called upon professional bodies to produce guidelines to support physicians defending themselves in court where foetal monitoring was an issue.

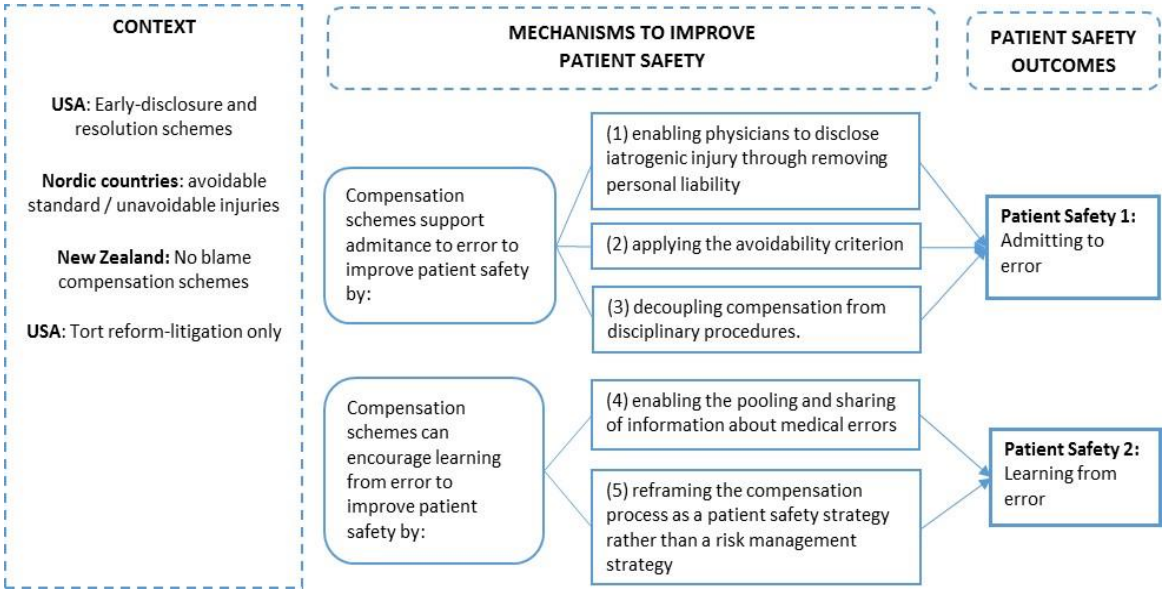
In the US, Dubay et al. (2001) investigated the role that negative defensive medicine played in the utilisation of prenatal care and the subsequent health of their infants for women from differing socio-economic backgrounds. This was measured by ethnicity, marital status and educational attainment. They did not find any substantial effects on infant health, but they did find that unmarried, lower-educated and black women were more likely to have fewer prenatal visits and less later care, since they were offered fewer appointments. These effects were ameliorated when insurance premiums were lower due to tort reforms. They concluded that reducing malpractice pressures enabled greater access to care for women who were more likely to be covered by Medicaid. They argued that, although the increased prenatal care did not improve the health of the infant and therefore could be considered 'socially wasteful', the costs of prenatal care would be more than offset by savings in unnecessary Caesareans offered to the women from the higher socio-economic categories.

One of the most common arguments for high malpractice pressure is that it leads to more cautious practice and therefore higher-quality outcomes. In the US, Yang et al. (2012) examined this deterrence effect in terms of birth outcomes and found that there was no difference in outcomes between states with tort reforms and those without. They argued that delivery methods prompted by malpractice pressures did not improve outcomes because the aim of the delivery choice was staving off liability risk rather than improving quality of care.

3.3.3 Patient safety

The conditions under which patient safety can be improved as a result of tort reform and/or the introduction of NFCSs is drawn from 10 papers. The two key outcomes identified in the literature focus on how different mechanisms can support clinicians to more readily admit to errors and the extent to which mechanisms can be put in place to enable learning from those errors (see Figure 3.3). Just over half of the papers reflect on the introduction of an NFCS in New Zealand (n=4) and schemes currently available in the Nordic countries (n=2).

Figure 3.3: Patient safety outcomes



3.3.3.1 Patient safety 1: Admitting to error

NFCSs 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.

The NFCSs stand in contrast to the tort system, where it is suggested that the dominant paradigm is more likely to be one of health professionals' silence, where claims of negligence against individual physicians can create strong feelings of guilt, a loss of self-confidence and damage to reputation (Mello et al. 2006). This can lead many clinicians to be reticent about sharing information about adverse events with patients, colleagues or the responsible authorities in health establishments. By removing individual liability, it is argued, NFCSs enable greater disclosure and increase the possibility of learning from medical error.

One reform of the tort system in the US has introduced the idea of holding institutions accountable for medical error, i.e. 'enterprise liability', rather than the individual physician (Kachalia et al. 2016). This liability reform takes into account any broader systems failures that may have contributed to claimants' injuries and so may influence improvements in procedures throughout the system. Since individual doctors are unlikely to have more than one malpractice suit against them in their career, but institutions, such as a hospital, are more likely to have multiple suits filed against them, then patterns of negligence may emerge which could point the way to possible system-wide improvements in patient safety.

Mello et al. (2006) advocate a move from negligence to an avoidability standard in order to reduce the psychological pressures of disclosure for doctors, where the notion of substandard care is replaced with one of suboptimal care. This change in standard accepts the possibility that avoidable injuries can happen despite the excellence of the physicians and the high quality of the care offered at hospitals.

In New Zealand and the Scandinavian countries, the compensation schemes are decoupled from disciplinary procedures. This enables doctors to disclose errors without damaging their reputations and their future careers. In the 2005 New Zealand reforms, the ACC was no longer required to report individual clinicians to professional disciplinary boards to establish medical error, as the eligibility criteria was changed to include all treatment injury. Before the reforms, Bismark and Paterson (2006) found that compensation procedures were delayed, as doctors defended themselves by withholding information as they challenged claims made against them.

The final removal of the fault-based criteria was also extended to the pre-existing duty to report all findings of medical error to the Medical Council, New Zealand's professional standards body for clinicians, and replaced with a new duty to report 'risk of harm to the public' and to the 'authorities responsible for patient safety' (Wallis 2013 p.34). Separating the compensation process from disciplinary procedures has arguably freed health care providers to disclose information about medical injuries and is more in line with 'the requirements of a no-blame culture of openness and learning as advocated by patient safety experts' (Wallis and Dovey 2011 p.587).

However, Wallis (2013) raises concerns about the decreasing numbers of doctors brought before disciplinary committees since 2005 and questions the apparent conclusion that there are few negligent doctors in New Zealand. From studies published at the turn of the century, Bismark and Paterson (2006) cite the rate of medical error in New Zealand as being comparable to adverse events in jurisdictions with similar health systems – a 12.9% adverse event rate compared to 16.6% in Australia and 10.8% in the UK – and so the New Zealand scheme does not seem to offer any particular advantages regarding patient safety. Wallis (2013) concludes that the decoupling of compensation and disciplinary processes has not led to increased openness and learning about injury, but there is also no evidence that the 2005 reforms have led to worse patient care. This unwillingness to admit to mistakes may also be a product of the professional culture of doctors as well as fears about peer ostracism and loss of reputation (Mello et al. 2006; Morreim 2004).

3.3.3.2 Patient safety 2: Learning from error

NFCSs 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.

The emphasis on establishing negligence under the tort-based system can lead to malpractice cases being seen as 'a random event not associated with quality', and therefore the litigation process misses the opportunity to support health care providers to 'understand the causes of avoidable injury and try to prevent recurrences' (Mello et al. 2006 p. 472). Administrative compensation schemes seek to reduce the pressure of tort liability which encourages a wall of silence about adverse outcomes, in order to increase the possibilities for learning from error.

No-fault schemes enable learning from error through the centralised compiling of error information as part of the claims process, and making this information available to interested parties, such as research and patient safety experts (Kachalia et al. 2016; Mello et al. 2006). In the tort system, information on medical error is often buried in a disparate and fragmented set of proprietary databases maintained by insurance companies and self-

insured health systems, which may not be accessible for research and quality improvement purposes (Kachalia et al. 2016). The adversarial nature of litigation procedures can also lead to a bias towards only collecting information on the process of care in relation to its relevance for proving cases of negligence rather than identifying failure in the health care system (Kachalia et al. 2016).

However, the issue of data relevance is also pertinent for administrative compensation schemes. Jonsson and Øvretveit (2008) assessed the scientific value of the data held on medical complaints and compensation claims available across three separate databases in Sweden.[5] They found that despite the extensive detail available in all three databases, the material's utility for learning about medical error was limited because the data was primarily used to assess eligibility in individual patient cases, and did not include the range of information needed to assess medical safety performance overall; the link between individual cases and wider patterns within the health system could not be made. In their conclusions, they considered the context of claiming, since more claims are made as patients become increasingly aware of their rights, so a rise in claims does not necessarily mean that health systems are becoming more unsafe. Patients are also claiming within the ever-changing medical system, where specialities may be transformed by the introduction of new treatments and drugs. Therefore, the type of claim may alter considerably over time.

The 2005 reforms made to the New Zealand compensation process sought to enhance its focus on 'systems learning' from medical error by ensuring that the scheme was not driven by a concern to assign blame to individual health practitioners but to enhance patient safety (Wallis, 2013). However, there were concerns that such a no-fault system, which decouples compensation from disciplinary procedures, would eliminate individual- and medical systems-level accountability and the learning that can be acquired from the complaints procedure. This led to the creation of the Office of the Health and Disability Commissioner to investigate complaints, often using mediation, to support further efforts to improve patient safety (Bismark and Paterson 2006). Increasingly, the commissioner has used strategies such as performance review and required training for doctors to rectify deficiencies in performance rather than the disciplinary process in his response to complaints (Wallis 2013). Thus the lack of disciplinary hearings may reflect this strategy rather than signal a less accountable system.

In the US, Hyman et al. (2010) evaluated a mediation programme designed to bring together plaintiffs and defendants to resolve disputes without resorting to the courts. They argued that since mediation took a problem-solving, collaborative, open-communication approach, it could support the exchange of information between patient and doctor and so increase patient safety. However, the approach borrowed heavily from the tort system and both parties were represented by lawyers during the mediation process. This made it impossible to reframe the process away from risk management towards a focus on patient safety, as the training and culture of the lawyers recreated the adversarial system of the court. Often only the lawyers were present, and usually neither the doctors nor the hospital representatives attended. Inevitably, the lawyers did not have

[5] The Medical Responsibility Board, which decides on disciplinary action when a complaint of negligence or malpractice is made; Patients Advisory Committees, which deal with a range of complaints made about health staff; and the Patient Insurance Fund, which holds case reports to establish if compensation is awarded.

the clinical training or experience to identify changes that could be made to improve safety, so opportunities for system change were missed. The authors reflected that even though hospital management staff took part sometimes, they maintained a risk management stance rather than patient safety perspective and therefore were not attuned to the options for change contained within the complaints.

The possibility of learning from malpractice claims is clearly affected by the claims process. The databases set up by the administrative systems enable an analysis that informs patient safety strategies (e.g. Pukk-Härenstam et al. 2008), but care needs to be taken about the conclusions that are drawn from the data. The adversarial nature of the tort system denies these possibilities since the risk management nature of the process excludes a patient safety approach.

3.3.4 Health outcomes

3.3.4.1 Introduction

Observations of claimants in compensation processes have documented their slower recovery to health as opposed to those who have not claimed or who are not compensable (Bhandari et al. 2008; Gabbe et al. 2007; Harris et al. 2008). The negative impact of litigation on health arises because claimants are encouraged to maintain their injured status in order to claim compensation, i.e. secondary gain, and they are exposed to the stress of medical examination, delays in decision making and the adversarialism inherent in the litigation process, i.e., secondary victimisation.

There seem to be few studies that directly measure the effects of NFCSs and tort reform on the health and well-being of claimants. This may be a result of the difficulties of establishing the impact of litigation on mental health and physical recovery. A key issue for this kind of research is establishing causality, since those in poorer health may be more likely to claim compensation rather than the compensation process leading to poorer outcomes. In this introduction, we summarise the research that has considered this impact before we go on to look at the studies that may contribute to our understanding of the impact of no-fault schemes.

Spearing and Connelly (2011) conducted a review of systematic reviews to examine the health effects of litigation and worker compensation schemes on claimants. The commonly held view that compensation schemes have deleterious effects on both mental and physical health could not be supported, they concluded, because of the quality of the research. The studies did not take into account the wide variation in schemes across different jurisdictions; they did not consider the *a priori* health status of the claimants, but relied on post-claim measures of health; and they used proxy measures of health, such as return to work and time to closure, which the authors questioned as suitable given that other factors may influence these events.

Similarly, Elbers et al. (2013) found that the low quality of studies in their review did not allow a confident conclusion about the link between the mental health of claimants and the compensation process. They found that the compensation group already had higher levels of mental illness at baseline in comparison to those who were not in the compensation process, and that this difference explained about three-quarters of the effect of compensation at post measurement. Additionally, the studies were highly

heterogeneous in terms of the type of compensation scheme, outcome measures and measurement points, and imprecise, with large confidence intervals and possible publication bias. However, they did conclude that the compensation process, specifically litigation, did not support claimants psychologically.

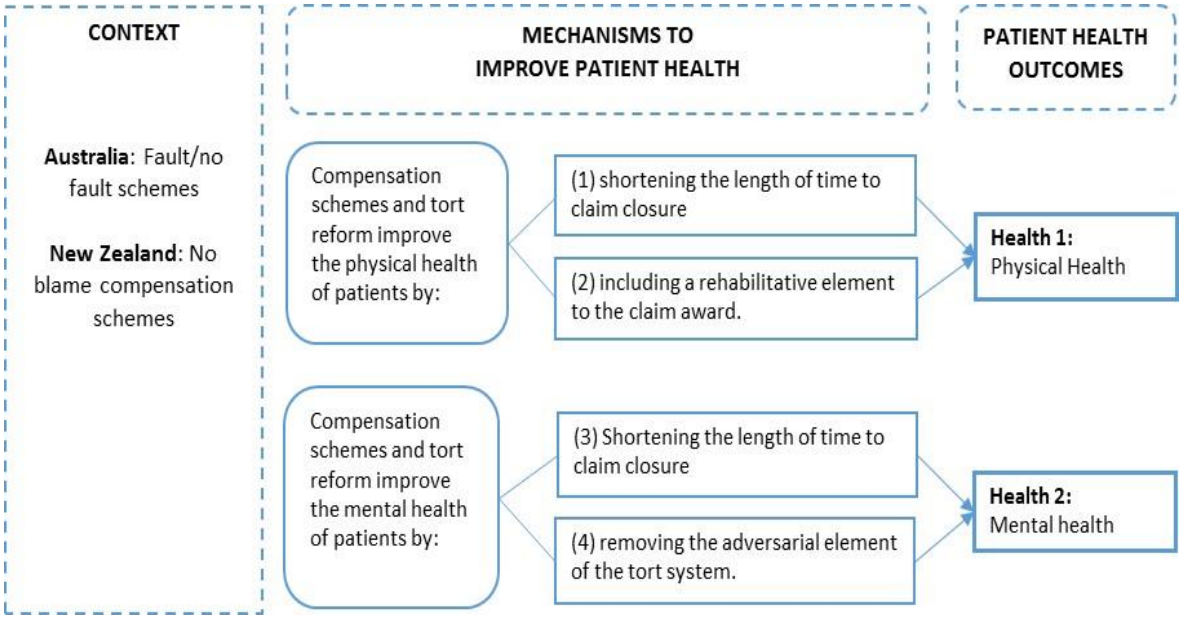
A later study by Grant et al. (2014), however, examined which aspects of the compensation process impacted on the mental well-being of people involved in car accidents and work-related injuries. They found evidence for increased levels of distress associated with: a lack of information about making a claim (33.9% of the cohort); time delays in the compensation process (30.4%); the number of medical assessments (26.9%); and the amount of compensation they received (26.1%). These levels of stress predicted poorer physical and psychological outcomes when the claimants were followed up six years later. Furthermore, Sterling et al. (2010) found that claim lodgement for those with whiplash injury was associated with increased post-traumatic stress disorder symptoms in all categories of claimant from resilient victims to those with severe symptoms, as well as increased neck disability in those with mild to moderate symptoms.

More recently, Murgatroyd et al. (2015) reviewed studies that had investigated physical and psychological effects of the compensation process on claimants who had suffered musculoskeletal injury. They were more confident in their conclusions that compensation status (making a claim) and the presence of a lawyer did explain some of the level of disability experienced by claimants and poor psychological function in studies of high and moderate quality. The effects on mental health were greater than those on physical health. However, they could not refute the possibility of bias due to reverse causality, since of the 13 out of 29 studies that measured baseline health, six found that this predicted recovery.

Type of studies

All of the studies (n=8) associated with these outcomes are concerned with compensation relating to accidents, mostly road traffic accidents, and none are related to iatrogenic injury. Some are concerned with accidents at work and are covered by worker compensation schemes. Most of these studies were conducted in Australia (n=6).

Figure 3.4: Patient health outcomes



3.3.4.2 Health 1: Physical health

NFCSs and tort reform improve the physical health of patients by shortening the length of time to claim closure and by including a rehabilitative element in the award.

Cameron et al. (2008) investigated the impact of tort reform in Australia for those suffering from whiplash. The reforms included restrictions on access to compensation for non-economic loss, the introduction of clinical guidelines for the management of whiplash, earlier acceptance of claims and greater provision of earlier treatment. In comparing claimants before and after the change in legislation, they asserted that there was a significant improvement in the health status of claimants after reform, in terms of disability, pain and physical functioning. However, mental functioning did not improve. They argued that the focus on rehabilitation had made a physical difference, but the psychological problems might continue to be present due the circumstances of the initial accident, which would remain unaffected by rehabilitation strategies.

Exploring the impact of the New Zealand no-fault scheme on physical functioning for those with spinal injury, Montgomery et al. (2015) found that there was no difference between those who were compensated and those who were not. They compared this finding with outcomes from papers reporting on worker compensation schemes. These had a litigious element and the time to settlement was usually longer. In these schemes, claimants had significantly poorer outcomes than those who did not claim. Since the ACC scheme improved the outcomes of litigious worker compensation schemes, we can conclude that the no-fault aspect of the schemes conferred some physical benefit on its claimants.

In the same study, Manson et al. (2015) reported on the return to work rates of those in the ACC scheme and found that they were similar to those who had not claimed in the papers looking at worker compensation schemes. In their conclusion, they argued that the more co-operative rehabilitative environment of the ACC scheme facilitated a quicker return to work. This is an important outcome, since longer periods away from the workplace mean a greater likelihood of never returning to employment.

Harrington et al. (2015) compared the experiences of victims of motor vehicle accidents with brain injury in Australian states with no-fault and fault-based schemes. In Victoria, all motorists must pay a transport charge at the time of driver registration. This no-fault scheme covers payment for acute care, rehabilitation and care and support services, as well as regular loss of income payments, allowances for dependants and family members, and impairment lump sum payments. In Queensland, access to funding for rehabilitation and support is dependent upon a compulsory third-party insurer accepting liability for a claim or agreeing to pay for services on a without-prejudice basis. Compensation for loss of income, pain and suffering and future suffering are awarded as a lump sum payment, often paid out several years after the injury. This can mean that claimants are reliant on private funds, other types of insurance and the pensions of carers if they cannot maintain their employment before their claim is settled.

The researchers interviewed adults with brain injury caused by motor vehicle accidents who were compensable and non-compensable to explore their experiences of these different types of compensation schemes (Harrington et al. 2015). Three themes emerged: rehabilitation-focused pathways vs resource-rationed pathways; a sense of security vs pressured lives; and bounded choices vs unknown choices.

In terms of rehabilitation, the victims and their families in Victoria had earlier and more comprehensive access to care, support and services. The focus of these services was to rehabilitate the victims so that they could live as independently as possible, and families received training to support this aim. Those in Queensland experienced pressures to quit hospital, since the insurance schemes would not necessarily fully pay for their care, if they were compensable. The insurance companies would pay for therapies but not necessarily access to therapies, which caused problems for rural families. Access to support and therapies were delayed as liability was established, and, in some cases this delay may have contributed to slower or partial recovery.

3.3.4.3 Health 2: Mental health

NFCSs and tort reform 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.

Few papers examined the effects of no-fault schemes on the mental health of victims. However, looking at the studies by Grant et al. (2014) and Sterling et al. (2010), we can reasonably conclude that the shortened time to claim closure and the removal of the adversarial element common to no-fault schemes would have beneficial effects. Only Gabbe et al. (2007) found that NFCSs were detrimental to mental and physical health when claimants were compared to non-claimants in Victoria. They suggested that the mental health detriment was due to the cause of the trauma for claimants, i.e. road traffic accidents, as opposed to falls in the non-compensable group. They surmised that traffic accidents could be more traumatic than falls and that this factor contributed to the finding. Although this would not apply to children in the context of their own birth injury, shortening the length of time to receive a claim could be of benefit to their parents or wider family.

Harrington et al. (2015) reported that families in the no-fault scheme in Victoria felt a sense of security that they would get help as long as they needed it. In contrast, families in Queensland, uncertain of compensation, experienced the pressures of caring for a dependant whilst they waited for settlement. Many gave up work to become a carer and suffered a loss of income.

The final concern, explored by Harrington et al. (2015), was the extent of choice offered by the Victorian scheme. This could be frustrating for some families if the governmental insurer refused to pay for less mainstream therapies, identified by the families as beneficial for their dependant. However, in Queensland, families were uncertain about what therapies were available and what the insurer would pay for. Only strong advocacy enabled greater choice in living arrangements for victims, but this disadvantaged those who were less able to argue for their case.

3.3.4.4 Health and well-being of medical professionals

We could find no studies that related the mental and physical health of doctors to tort reform or NFCSs. We found studies that explored midwives' experiences of litigation (Robertson and Thomson 2014, 2016; Symon 2000), doctors' reactions to disciplinary (Verhoef et al. 2015) and complaints procedures (Bourne et al. 2015), and midwives' feelings about a review and inspection process (Hood et al. 2010). These processes, often influenced by litigation practices, caused feelings of anger, shame and misery for the clinicians and nurses. They experienced a loss of confidence in their abilities (Robertson and Thomson 2014) and some doctors claimed greater use of defensive medicine as a result (Bourne et al. 2015).

We must assume a consensus among researchers that no-fault schemes will benefit the health and well-being of doctors and nurses, or not damage their health, at least. Tort reforms directly benefit doctors economically in the USA since they tend to lower the insurance premiums for doctors. The extent of the benefit to well-being may be tempered by the high expectations of themselves that doctors and nurses hold, so that criticism and fault finding may be particularly costly to them, psychologically, whether liability is established or not.

4. Discussion and conclusions

4.1 Summary of key context, mechanisms and outcome configurations

Our review aimed to develop preliminary theoretical frameworks of the mechanisms influencing engagement in NFCSs. We used a realist approach to understand the connections through which different components of NFCSs, operating under certain social and political systems, are thought to influence outcomes concerning access to justice, clinical practice, patient safety and patient health. The following presents a summary of our findings, which provide a justification of the CMO configurations based on our analysis of the papers. We conclude the chapter with a discussion of the implications from our CMO configurations.

Firstly, we found varied conceptions of the notion of NFCSs. We accepted papers that discussed the effects of tort reform on the insurance system although these were far from no-fault schemes. We did this where the effects of tort reform were comparable to no-fault schemes, for example where the effect of lessening of malpractice pressure on doctors and the subsequent impact on defensive medicine were similar to mechanisms in no-fault schemes of the decoupling of compensation and disciplinary procedures (Vandersteegen et al. 2015).

Liability was the key variable in the schemes and the concept of blame shaped the schemes profoundly. In France, the compensation scheme was an expression of solidarity with individuals who had suffered major injury (Barbot et al. 2014), but retained the notion of blame and the litigation process for those patients who could establish liability. In New Zealand, the country to most clearly dispense with blame, the scheme operated like a targeted social security benefit programme with its broad eligibility criterion of ‘treatment injury’ (Kachalia et al. 2008). In the United States, tort reform seemed to be the reluctant consequence of a breakdown in the compensation system when doctors could no longer afford the insurance premiums and were leaving the profession (Kessler n.d.). These reforms seemed highly contested, with studies competing to show that there were large or no effects of these reforms. This research may reflect an anxiety about reducing the accountability of the medical profession and restricting access to legal redress.

Evidently, the schemes were a product of their jurisdictions. In New Zealand and Scandinavia, with their universal health care provision, the creation of a state-run compensation scheme fitted with their conception of health care as an important provision by central government. In the United States, there was understandable reluctance to deny claimants the possibility of attaining damages through the court process since there was less of a social security safety net to support individuals with ongoing ill health and disability.

Many of the writers in this sample were critical of the tort system and its role in the compensation process. They described it as imprecise, since some undeserving claimants were successful, and many deserving cases were unsuccessful, and commented that in some social jurisdictions without access to legal aid, it was unfair, favouring those who could afford to pay for expensive lawyers and discriminating against the poor. There were

damaging effects on claimants, on their physical and mental health (e.g. Grant et al. 2014; Sterling et al. 2010), and on their incomes. The tort system caused distress for doctors and nurses, causing early exits from the profession, long-term sick leave (Robertson and Thomson 2014) and claims by doctors of a greater likelihood of practising defensive medicine (Bourne et al. 2015). There were costs to the health system as a whole, particularly in the defensive practices of over-ordering of tests and conservative treatments as clinicians sought to protect themselves against malpractice suits. Further, negative defensive medicine contributed to inequalities in health systems.

The empirical research attempted to test out the effect of no-fault schemes and tort reform on these issues. This research alongside more theoretical contributions, enabled the development of propositions which explained the observed effects of no-fault schemes and tort reform when they were compared to the tort system. These explanations gave reasons for: the more precise targeting of compensation (Davis et al. 2002); the impacts on physical and mental health outcomes (Cameron et al. 2008; Montgomery et al. 2015) and health system costs (Vandersteegan et al. 2015); the more equitable access to justice (Bismark et al. 2006a, 2006b) and health care (Dubay et al. 2001); the importance of procedural justice (Siegal et al. 2008); the possibilities of improved patient safety (Wallis 2013); and the limited information on medical error (Wallis 2015). There was a lack of studies regarding the physical and mental health impacts of no-fault schemes where the claimants had suffered an injury as a result of medical treatment. The mental health detriment suffered by those experiencing injury through medical error may be greater than those injured in car accidents, since iatrogenic injury may represent a breakdown in trust not experienced by car accident victims.

4.2 Strengths and limitations

The process we adopted aimed to focus on the needs of policy makers as they considered different policy options, and allowed for iteration as researchers and policy makers considered the most relevant issues for exploration. Using this process, we developed our CMO configurations in consultation with the policy team at the DH. This suggested a greater focussing on justice, health and clinical outcomes, which narrowed down our searching and supported a deeper engagement with issues of current relevance to the team.

As in all realist reviews, we relied on snowballing techniques, picking up terms in papers as we read them in order to use them in limited searches, as well as mining papers for citations and searching for papers that cited included studies. In this respect, the process of identifying the studies to include in the review is not entirely replicable.

Throughout the review, the team engaged in discussions about the included papers in order to refine the CMOs and to check our understanding of the arguments, results and conclusions of the papers. Two researchers carried out data extraction on the included studies and met to discuss the clarification of the initial CMOs, the structuring of the evidence and the contribution of each of the papers. We have not assessed the studies for quality but we have assessed them for relevance to the review questions. This was an appropriate approach in this review, as we were not using the papers to determine cause and effect, but to identify the range of possible mechanisms that might influence engagement in NFCSs. The papers are not directly comparable since some are empirical

studies, some are policy reviews and one uses economic modelling; we did not include opinion pieces, commentaries or editorials as we found the most useful studies to be those with some evidential basis.

4.3 Implications

This group of studies suggests that NFCSs can confer benefits on key stakeholders, namely patients, health professionals and the health system as a whole. The possible benefits range from improved targeting of compensation to those most deserving of it, to speedier physical recovery after injury.

However, the complexity of the interactions between compensation processes, individual circumstances and the health systems in which the schemes are embedded make it difficult to establish strong causal pathways, most notably regarding health outcomes.

The shape of the schemes will be highly influenced by the health system context which, in turn, is affected by the prevailing political opinion about the role of the state in health care.

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Part II Technical description of the review

6. Detailed methods

This chapter describes in more detail the methods used to conduct the review. Here we provide a more detailed account of the iterative methods used to conduct the first part of a realist approach in a short policy time frame. The review was conducted in overlapping stages in order to focus on particular issues identified by the UK Department of Health as being most relevant for its needs.

6.1 Type of review: realist theory development

Similar to existing realist reviews, such as Molnar et al. (2015 p.2), we sought to facilitate 'a deeper understanding of the mechanisms that connect the context' of no-fault compensation schemes with differing outcomes. The review aims and questions are well-suited to an examination of mechanisms triggered by context, as we consider different types of fault-based and no-fault compensations schemes, in existence across a range of social jurisdictions, to explore how they might achieve greater uptake and improved outcomes. Typically, realist reviews contain two distinct phases: 1) the identification of the context, mechanisms and outcome configurations (CMOs); and 2) the identification and analysis of literature that seeks to tests those theoretical configurations. To fit within a specific policy time frame (December 2015 to April 2016), we drew on rapid realist methods (Saul et al. 2013) and focus solely on the first part of a realist review: the initial CMO theory development. However, we also provide a justification and, to support the development of preliminary CMOs, theoretical frameworks.

This review was conducted in overlapping and iterative stages: 1) initial searching and defining of the scope of the review through concept mining and framework formulation; 2) iterative searching and screening of primary studies; 3) assessment of relevance and data extraction of papers; and 4) evidence-informed CMO framework theory development (Rycroft-Malone et al. 2012; Saul et al. 2013).

6.2 User involvement

Consultation with key stakeholders is considered important to the production of a relevant piece of research (Rees and Oliver 2012; Saul et al. 2013). However, the short timeline necessitated a limited amount of public consultation to inform this realist review. Instead we undertook several discussions with key policy leads within the Department of Health responsible for medical litigation. Meeting regularly with the policy leads and commissioners throughout the review process enabled us to ensure that the review is closely aligned with their needs and emerging policy requirements. The initial meeting included a discussion of the scope and key challenges of the topic area, namely the lack of UK evidence in birth injury, leading to the broadening of the review criteria to draw on a wider evidence base extending to medical and non-medical injury. In subsequent meetings based on the initial scoping we were able to present some initial CMO configurations and narrow the focus to their particular outcomes of interest. We also circulated and met to discuss interim CMO configurations by outcome to ensure that the structure and content of

the configurations and their explanatory text was useful and in line with their expectations. By submitting draft findings in advance, as available, we could thus use the feedback in the next explanatory account of the CMO configurations, shaping the overall report.

6.3 Stage 1: Defining and scoping the evidence: concept mining and framework formulation

6.3.1 Conceptual framework and preliminary CMO framework

The initial conceptual framework guiding the examination of factors potentially influencing uptake of compensation schemes was based on the key features of schemes identified in the review by Farrell et al. (2010 pp.8-9). These include:

- eligibility and threshold disability criteria
- limitations to the extent of cover
- levels of entitlements
- simpler and more comprehensive access to justice
- restricted access to courts
- the existence of a comprehensive national social welfare/social insurance system.

During the protocol development, we began by taking the key features outlined above, and read some key studies to develop initial hypothetical configurations between CMOs (see Table 6.1). These example CMOs appeared in the protocol. We defined and understood context to consist of the compensation schemes for injuries occurring during birth and early childhood or in other comparable injury-related contexts, as they are played out in Western societies. Mechanisms included the factors potentially contributing to claimant engagement with compensation schemes, in addition to other types of mechanisms triggered by the ways compensation schemes might be designed and implemented.

Table 6.1: Initial conceptual framework: Context, intervention mechanisms and types of outcomes: Examples of CMO configurations

Context: Compensation schemes which vary by eligibility criteria (definitions of 'fault'), compensation entitlement levels and extent of cover and how decisions are made (in comparison with the court system)

Mechanism	Outcome
Broadly defined as notions of 'no-fault'. For example, in New Zealand this may result in more successful claims of lower amounts, and more narrow definitions of 'no-fault', whereas in France, it may result in fewer claims of larger amounts. The most severe disability only is compensated in France. Thus the compensation scheme in France may adequately care for long-term disability whilst in New Zealand, short-term care may be achieved.	Reduction in short- and long-term poverty due to caring for a disabled child
Economic damages, given for lost wages and medical expenses not covered by other insurance, are lower in countries where other forms of social insurance exist, such as the Nordic countries. The expectation is that the general safety net, as well as the compensation scheme, will prevent families falling into poverty.	

The transparency of the decision-making process, including the use of expertise and precedent and easily applied criteria, increases the perception of fairness and improves access to justice.	Greater and more equitable access to justice
If claimants have access to the courts as well as the NFCS, there may be lower numbers of claims using the no-fault scheme. For example, if there is no access to the courts, as in New Zealand and the Nordic countries, there are higher rates of application to the schemes, compared to France, which retains access to courts.	
Speedier decision making aids physical recovery, as claimants do not delay treatment because they are in the compensation process and need to show suffering and pain in order to gain compensation.	Mental health and well-being
Procedural justice, i.e. the process of decision making is perceived to be fair, impacts on mental health and physical well-being.	

We then read more broadly to come up with a longer list of CMOs connected to economic, justice and health outcomes. We shared these with the DH policy team, who were asked to prioritise the outcomes that they were particularly interested in exploring further. They asked us to focus on the justice and health outcomes, since the economic ones would 'would be considered through detailed economic modelling. We explored these outcomes further through more in-depth reading and discussion. These were then expanded into the final list of outcomes.

Table 6.2: Initial claimant outcomes

Context: Compensation schemes which vary by eligibility criteria (definitions of 'fault'), compensation entitlement levels and extent of cover and how decisions are made (in comparison with the court system) in varying jurisdictions.

Prioritised outcomes in bold

Outcome	Mechanism
ECONOMIC 1: Generous payouts	Compensation entitlement levels and limitations on the extent of cover impact on the risk of falling into poverty since they may not be generous enough to take care of the child over the long term.
ECONOMIC 2: economic damages and social welfare regimes	Economic damages, given for lost wages and medical expenses not covered by other insurance, are lower in countries where other forms of social insurance exist, such as the Nordic countries. The expectation is that the general safety net, as well as the compensation scheme, will prevent families falling into poverty.
ECONOMIC 3: Broad eligibility criteria equal many claims, which equal small payouts	Broadly defined notions of 'no-fault', e.g. in New Zealand, may result in more successful claims of lower amounts; narrower definitions of 'no-fault', e.g. in France, result in fewer claims of larger amounts. Only the most severe disability is compensated in France. Thus the compensation scheme in France may adequately care for long-term disability, whilst in New Zealand, short-term care may be achieved.
ECONOMIC 4: Return to work	Compensation schemes with generous terms and broad eligibility criteria and a rehabilitation focus enable an earlier return to work and so make it less likely that families will fall into poverty.
ECONOMIC 5: Earnings related compensation only	No-fault compensation schemes that only pay compensation on lost earnings target those in the workforce. It dissuades older people, who may have more severe injuries, from applying.

JUSTICE 1: Access to courts	**If claimants have access to the courts as well as the NFCS, there may be lower numbers of claims in the no fault scheme, as in France. If there is no access to the courts, there are higher rates of application to the schemes, as in New Zealand and the Nordic countries.**
JUSTICE 2: Equality of access	**Compensation entitlement levels impact on access to justice if greater sums can be gained through access to the courts – so only those wealthy enough to afford a lawsuit can pursue claims that may, if successful, lead to higher sums. However, the no fault schemes ensure access to compensation no matter the income level of the applicant.**
JUSTICE 3: Patient groups increase the democratic mandate of decision making	The make-up of the decision-making committees will affect access to justice. The presence of patient groups increases the democratic mandate of the committees and makes the decisions more acceptable.
JUSTICE 4: Compensation decoupled from disciplinary procedures	**Creating a 'Chinese wall' between compensation procedures and disciplinary procedures enables speedier access to justice, since physicians are more ready to hand over the relevant information.**
JUSTICE 5: Transparency of decision making	**The transparency of the decision-making process, including the use of expertise and precedent and easily applied criteria, increases the perception of fairness and improves access to justice.**
JUSTICE 6: Severity of harm criterion	No-fault compensation schemes with eligibility criteria relating to severity of harm are likely to cover all these adverse events.
JUSTICE 7: Preventability criterion	NFCSs with eligibility criteria based on preventability criteria, as in the Nordic schemes, tap into patient dissatisfaction and identify nearly all events that have system-related aetiologies.
JUSTICE 8: Cerebral palsy	Cerebral palsy is the only birth outcome associated with malpractice (other than death). Therefore, an NFCS that covered this injury comprehensively would ensure access to justice for all.
HEALTH 1: Generous pay-outs to increase security	**Compensation entitlement levels that are generous improve the mental health of recipients, since they are reassured that they are not at risk of falling into poverty.**
HEALTH 2: Improved access limiting anxiety	**Broad eligibility criteria improve access to justice and remove the anxieties of fighting a court case, and thus improve mental health and well-being.**
HEALTH 3: Speedy decision making	Speedier decision making improves well-being, as it means that the money is released earlier and there are fewer anxieties about court cases.
HEALTH 4: Procedural justice	Procedural justice, i.e. the process of decision making is perceived to be fair, impacts on mental health and physical well-being.
HEALTH 5: Speedy decision making aids physical recovery	Speedier decision making aids physical recovery as claimants do not delay treatment because they are in the compensation process and need to show suffering and pain in order to gain compensation.
HEALTH 6: Improves physical outcomes	**NFCSs improve physical outcomes.**
HEALTH 7: Limited choices	Limited choices in what services can be provided under an NFCS improve information about what is available and appropriate, and reduce anxieties associated with choice.
HEALTH 8: No need to prove injury aids recovery	The universality and absence of need to prove injury and disability to obtain compensation also favour a positive environment for functional recovery.
HEALTH 9: Rehabilitation focus aids return to work	No-fault compensation schemes, with additional support workers to promote return to economic life, aid recovery.

In the final list, the prioritised CMOs were adjusted and the explanations sharpened, and the remainder were either subsumed into or discussed under the final configurations.

Table 6.3 indicates how these initial CMOs were reorganised under the final configurations.

Table 6.3: Final CMOs with contributions from initial CMOs (*Subsumed CMOs are in italics)*

Outcome	Mechanism
JUSTICE 1: Access to Court	To ensure that compensation schemes remain attractive to claimants, they must offer payments comparable to damages awarded through litigation, and broader eligibility criteria, to ensure that they are more appealing than the tort-based system.
JUSTICE 2: Equality of Access	NFCSs that are free to access improve justice outcomes in that they are accessible to all eligible parties, unlike the tort system, which favours those who can afford legal representation.
JUSTICE 3: Transparency of process	Transparency of process achieves justice through the representation of the claimant, and mechanisms that improve the consistency of decision making through the use of medical experts and the consideration of precedents. The initial CMO: 'JUSTICE 3: Patient groups increase democratic mandate of decision making' was discussed under this CMO
JUSTICE 4: Compensation processes decoupled from compensation procedures	Creating a 'Chinese wall' 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.
JUSTICE 5: Severity of harm criterion	This criterion was discussed under JUSTICE 1.
JUSTICE 6: Preventability criterion	The notion of preventability was picked up in the Patient Safety outcomes, which discussed admitting and learning from error.
JUSTICE 7: Cerebral palsy	The issues concerning adjudications around cerebral palsy and the need for medical experts were discussed under JUSTICE 3.
HEALTH 1: Physical Health	NFCSs and tort reform improve the physical health of patients by shortening the length of time to claim closure and by including a rehabilitative element in the award. This was developed from HEALTH 6.
HEALTH 2: Mental Health	NFCSs and tort reform 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. HEALTH 1 and 2 were combined to form this CMO.
HEALTH 3: Speedy decision making	This theme, as it effects mental health, was discussed in HEALTH 2.
HEALTH 4: Procedural justice	This was discussed under JUSTICE 3 and HEALTH 2.
HEALTH 5: speedy decision making aids physical recovery	This was discussed under HEALTH 1.
HEALTH 6 Limited choices	This was discussed under HEALTH 2.
HEALTH 8: No need to prove injury aids recovery	This was discussed under HEALTH 2.
HEALTH 9: Rehabilitation focus aids return to work	This was discussed under HEALTH 1.

We were also asked to consider outcomes affecting clinicians and we went through the same process, preparing a list of candidate CMOs and asking the policy team to prioritise. They identified areas of interest within these outcomes, but also wanted to know if there

was any information about how no-fault schemes affected the well-being of clinicians. In the short time available we could not find any papers about this and so wrote a short note about the effects of the tort system on clinicians.

Table 6.4 sets out our initial CMOs regarding clinical practice and patient safety and table 6 shows how these initial CMOs were discussed under the final three configurations that were developed.

Table 6.4: Clinician outcomes – initial CMOs

Outcome	Mechanism
CLINICAL PRACTICE 1: Caps on damages enable riskier treatments	Caps on non-economic damages (pain and suffering) lead to treatments with higher risk and also higher survival rates (e.g. bladder cancer). The higher survival rates are due to more experienced care after the risky surgery.
CLINICAL PRACTICE 2: No-fault schemes lower health costs	No fault schemes, where there is no personal liability for the doctor, reduce the need for defensive medicine in terms of precautionary procedures, and so lower health treatment costs.
CLINICAL PRACTICE 3: Caps on damages affect referral rates	Caps on non economic damages lower referral rates received by specialist doctors.
CLINICAL PRACTICE 4: Reductions in liability do not affect birth outcomes	The impact of liability pressure on obstetric practice comes largely in the form of defensive medicine. The rise in Caesarean sections and the dip in vaginal births after Caesareans induced by liability pressures (Yang et al. 2009) cannot be justified on clinical grounds, and the liability pressures produce patterns of precaution taking in obstetrics that do not lead to superior birth outcomes.
PATIENT SAFETY 1: Admitting to error	Removing the stigma associated with negligence investigations and findings could make providers more comfortable discussing and admitting errors, in turn supporting learning and prevention.
PATIENT SAFETY 2: Learning from error	Evidence suggests that system administrators make good use of their databases to identify safety problems and that they disseminate lessons learned nationally.
PATIENT SAFETY 3: Physicians more likely to disclose	In a no-fault system where there is no personal liability, physicians are more likely to disclose iatrogenic injury.
PATIENT SAFETY 4: Process is about patient safety rather than risk management	By avoiding the litigation process where negligence is identified, the no-fault compensation scheme enables a greater focus on patient safety rather than risk management. A system involving lawyers implies a risk management strategy which puts barriers in the way of patient safety.
PATIENT SAFETY 5: Avoidability standard preferable to negligence standard	The avoidability standard removes the taint of negligence, and therefore makes it more likely that doctors will disclose injuries.

In the final three CMOs, all of the Clinical Practice CMOs were collapsed into the CMO labelled 'Defensive medicine' and the first two Patient Safety CMOs incorporated the last three CMOs in this group.

Table 6.5: Outcomes for clinicians: Final CMOs (*The subsumed CMS are in italic)*

Outcome	Mechanism
CLINICAL PRACTICE: Defensive medicine	Tort reform and NFCSs reduce unnecessary tests and procedures and improve access to health care for patients considered 'riskier' by clinicians because doctors are less likely to practise positive and/or negative defensive medicine to protect themselves from litigation.

	All four of the initial CMOs in this section were collapsed into this one overarching CMO.
PATIENT SAFETY 1: Admitting to error	NFCSs 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	NFCSs 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.
PATIENT SAFETY 3: Physicians more likely to disclose	This was discussed under PATIENT SAFETY 1.
PATIENT SAFETY 4: Process about patient safety rather than risk management	This was discussed under PATIENT SAFETY 2.
PATIENT SAFETY 5: Avoidability standard is preferable to negligence standard	This was discussed under PATIENT SAFETY 1.

6.4 Stage 2: Identification and retrieval of studies

6.4.1 Initial searching

To inform this review, an initial scoping exercise was undertaken in December 2015 (see appendix 2), in which Google Scholar was searched and key policy contacts provided literature on birth trauma and other international and UK-based compensation schemes for obstetrics and other types of medical injury. The initial identification of information helped to describe the characteristics of international no-fault injury compensation schemes and informed the conceptual framework, the development and refinement of the scope of the review and the review question outlined in Chapter 1. A further search for evidence was also undertaken covering the last 10 years in two key databases (see Section 6.4.2).

6.4.2 Further iterative searches

The literature search was iterative and ongoing throughout the review. To identify papers examining mechanisms influencing outcomes and the uptake of compensation schemes, a search was conducted on two academic databases MEDLINE and CINAHL, in January 2016. The terms used were ‘compensation schemes’ OR key terms related to compensation schemes identified from the initial scoping in phase 1, combined with concepts related to factors, barriers, facilitators and uptake. Searches were limited to the last ten years and the English language. Located citations were uploaded into EPPI-Reviewer, a custom research software, for management of publication retrieval, coding and synthesis (Thomas et al. 2010). We used the data-mining and independent search functions of EPPI-Reviewer to identify relevant papers. Single and combined terms used included, but were not limited to: ‘compensation scheme’; ‘no-fault’, ‘birth injury’, ‘early resolution’, tort reform. These searches were subject to screening against the inclusion criteria.

Overall, we sought reviews of policies introducing or commenting on NFCSs as a way of generating CMOs and of finding papers with empirical material that could support these CMOs. This search was supplemented by applying the same approach to Google Scholar. After further discussion with the DH in February 2016, further searches were carried out to

find additional articles capturing clinical outcomes. In addition, reference list checks and forward citation chasing were also undertaken to identify any other relevant literature.

The discussions with the policy team enabled more limited searches as we focused on the areas of interest. For example, the term 'defensive medicine' only emerged after papers were sought that identified the effects of compensation schemes on clinical practice. This term was not used in the earlier scoping searches, partly because our initial focus was on patient outcomes.

6.4.3 Selection of studies for inclusion in the review

We allowed refinement of the inclusion criteria to occur at any point during the review process in line with a realist approach, as this could reflect a greater understanding of the type of evidence most relevant to answering the review questions, or new conceptual and theoretical developments arising from the initial scoping in phase 1. In the case of this review, after discussion with policy makers, the criteria were expanded to include outcomes relevant to both patients and doctors. To be eligible for inclusion in this review, papers needed to do the following:

- Focus on an NFCS, relevant to potentially iatrogenic injuries in children occurring at birth or in the early years (under five years of age), or which have two of the three characteristics similar to birth trauma compensation schemes, including those that: are high-value claims, have high long-term costs, are highly emotive.

  These were an important guide initially, but we found that papers did not make these kinds of judgements about the injuries suffered by claimants. So we used papers that attempted to show the effects of compensation processes on victims whatever their injury, but prioritised papers that discussed birth injury and iatrogenic injury.

- Examine contextual factors influencing the delivery mechanisms of schemes that could contribute to uptake *and/or* contribute to our understanding of the CMOs, i.e. contain information about the effects of compensation schemes on economic, access to justice and health outcomes for victims and/or patients.

  This became the most important inclusion criteria. To be included, the papers had to tell us something about variations to the tort system that impacted on patients and/or doctors. Following discussion with the DH policy team we de-prioritised material pertaining to economic outcomes, which was considered elsewhere.

- Be published within the past ten years.

  This timescale identified literature most relevant to the UK context since the introduction of both the Making Amends report and the NHS Redress Act 2006, both of which dealt with medical liability reform (Department of Health 2003; UK Parliament 2006).

  We expanded this timeframe if papers contained relevant information that added to our understanding of the CMOs. However, the basic search strategy meant that such material was less likely to be identified.

6.5 Stage 3: Coding and analysis

6.5.1 Data extraction

Descriptive characteristics were extracted from the studies. Specifically, what type of NFCS and country the study investigated and whether the injury was medical or non-medical. Further empirical and descriptive information from the studies was extracted, drawing on the initial conceptual framework outlined in Section 6.3. Newly identified concepts were added to this framework as they appeared in the literature (see Appendix 2 for the coding tool).

6.5.2 Appraisal of relevance

Papers were critically appraised as their concepts were integrated into the initial framework. A common approach to quality appraisal in systematic reviews is to assess bias or rigour according to key dimensions of the design and execution of the study, and thus is undertaken prior to the synthesis. Quality appraisal in realist reviews is not solely based on methodological quality; it also relates to the relevance of the material for elucidating CMOs. The criteria for quality becomes whether the paper fits the needs of the review and the richness of the material found within the paper. As this review was only developing the CMOs, not testing them, studies were judged based on their relevance only.

We developed specific criteria to assess the relevance of papers to answer the review questions. First, we made an assessment of whether the paper sought to investigate, explore or describe the implementation or introduction of no-fault compensations schemes for birth injury, medical injury or other types of injuries (e.g. workplace or road traffic accidents). Second, we assessed whether the paper provided information or empirical evidence on uptake or on any one of the CMOs, e.g. sufficient explanation of why compensation schemes, or their different mechanisms, led to particular outcomes.

Based on answers to these questions, an overall judgement of high, medium or low relevance was made. Evidence was considered to be of high relevance when providing empirical evidence on birth-related injuries, medium relevance when related to compensation for other medical related injuries and low relevance when the focus was not medically related or when speculations from the authors were unsupported by empirical evidence. Overall, speculations alone were not included in the syntheses as they were judged not to be evidenced (O'Campo et al. 2015), such that we excluded opinion pieces, editorials and commentary.

6.5.3 Development of CMO configurations

Empirical and descriptive data from studies on the way different factors appeared to affect uptake and engagement in NFCSs and the manner in which they operated were combined from individual studies (Oliver et al. 2008; Thomas et al. 2012) to inform the development of context-mechanism-outcome configurations and explanatory accounts to support them. Our initial work focused on refining the CMOs so that they were as practically specific as they could be. This was made possible through reflective discussion between two reviewers (KD and KH) to consider the empirical and descriptive data extracted and whether they supported the CMOs, and where refinements and adjustments needed to be made. Evidence to provide the narrative justification of the preliminary theoretic CMO configurations was identified from the findings, authors' descriptions of findings and their conclusions. This write-up of the studies against these CMOs aimed to

clarify and substantiate our thinking about why we had structured the CMO in this way and to justify the configurations as they are presented in the report. We aimed to ensure that each CMO configuration began with the way differences in compensation schemes across social jurisdictions (context) might trigger or shape engagement or practice (mechanisms) and affect patients and clinicians (outcomes). Although using EPPI-Reviewer allowed us to maintain a record of initial CMOs and produce evidence tables and supporting evidence that could be shared between reviewers, and although in some cases we did attempt to go back and record further CMOs, each iteration of the CMOs was not formally recorded.

Overall, our analysis sought to identify and report on the way compensation schemes may be related to access to justice, clinical practice, patient safety and health outcomes, both physical and mental. We interrogated the studies to ensure that we were able to identify and report on the extent to which the empirical literature supports the CMOs that we had identified with our policy colleagues. The content and implications of the analysis for potential birth trauma compensation schemes will be used for the basis of team discussion and to inform decisions about how this review might be taken further.

6.5.4 Quality assurance process

This rapid realist review draws on EPPI-Centre quality assurance processes at two key stages in the review. At the study selection stage, reviewers discussed in detail a sub-set of papers potentially relevant to informing the CMO framework in terms of their richness, depth and level of empiricism. All papers selected for inclusion were checked by a second reviewer to confirm that they met the criteria for inclusion and relevance. At the analysis stage, reviewers independently extracted data for each potential CMO and met to discuss their initial ideas, refining the CMOs in light of this discussion. Further, using EPPI-Reviewer (Thomas et al., 2010) as a database system enabled us to keep a transparent record of the identification and coding of studies found during the review, including any refinements that were introduced through the review process.

Appendices

Appendix 1: Rapid realist review checklist

Section	Checklist items		Reported
Title			
1		In the title, identify the document as a realist synthesis or review	Title page
Abstract			
2		While acknowledging publication requirements and house style, abstracts should ideally contain brief details of: the study's background, review question or objectives; search strategy; methods of selection, appraisal, analysis and synthesis of sources; main results; and implications for practice.	Executive summary
Introduction			
3	Rationale for review	Explain why the review is needed and what it is likely to contribute to existing understanding of the topic area.	Chapter 1
4	Objectives and focus of review	State the objective(s) of the review and/or the review question(s). Define and provide a rationale for the focus of the review.	Chapter 1
Methods			
5	Changes in the review process	Any changes made to the review process that was initially planned should be briefly described and justified.	Chapter 6 – review inclusion only
6	Rationale for using realist synthesis	Explain why realist synthesis was considered the most appropriate method to use.	Chapters 1 and 2
7	Scoping the literature	Describe and justify the initial process of exploratory scoping of the literature.	Chapter 6
8	Searching processes	While considering specific requirements of the journal or other publication outlet, state and provide a rationale for how the iterative searching was done. Provide details on all the sources accessed for information in the review. Where searching in electronic databases has taken place, the details should include, for example, name of database, search terms, dates of coverage and date last searched. If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified and selected.	Chapter 2; Appendix 2

Section	Checklist items		Reported
9	Selection and appraisal of documents	Explain how judgements were made about including and excluding data from documents, and justify these.	Chapter 6
10	Data extraction	Describe and explain which data or information were extracted from the included documents and justify this selection.	Chapter 6
11	Analysis and synthesis processes	Describe the analysis and synthesis processes in detail. This section should include information on the constructs analysed and describe the analytic process.	Chapter 6
Results			
12	Document flow diagram	Provide details on the number of documents assessed for eligibility and included in the review with reasons for exclusion at each stage as well as an indication of their source of origin (for example, from searching databases, reference lists and so on). You may consider using the example templates (which are likely to need modification to suit the data) that are provided.	N/A – only conducting first part of realist review in a rapid time frame.
13	Document characteristics	Provide information on the characteristics of the documents included in the review.	Appendix 3
14	Main findings	Present the key findings with a specific focus on theory building and testing.	Chapter 3
Discussion			
15	Summary of findings	Summarise the main findings, taking into account the review's objective(s), research question(s), focus and intended audience(s).	Chapter 4
16	Strengths, limitations and future research directions	Discuss both the strengths of the review and its limitations. These should include (but need not be restricted to) (a) consideration of all the steps in the review process and (b) comment on the overall strength of evidence supporting the explanatory insights which emerged. The limitations identified may point to areas where further work is needed.	Chapter 4
17	Comparison with existing literature	Where applicable, compare and contrast the review's findings with the existing literature (for example, other reviews) on the same topic.	N/A – only conducting first part of realist review in a rapid time frame.
18	Conclusion and recommendations	List the main implications of the findings and place these in the context of other relevant literature. If appropriate, offer recommendations for policy and practice.	Chapter 4 – partially as only conducting first part of review

Section	Checklist items		Reported
19	Funding	Provide details of funding source (if any) for the review, the role played by the funder (if any) and any conflicts of interests of the reviewers.	Title pages

Note: adapted from Wong et al. (2013)

Appendix 2: Methods

Initial scoping search strategy

Search strategy for Medline via OVID, run 18 December 2015.

Systematic review terms: (S1)

NFCS terms (S3-9)

Date limit of 2005-2015 (S2, S10).

Searches	Results	Hits
1	"systematic review".kw. or meta-analysis.pt. or meta-analysis.ti. or meta-analysis.ab. or meta-analy*.tw. or "systematic literature review".ti. or "systematic literature review".ab. or review.pt. or "meta synthesis".ti. or "meta synthesis".ab. or "integrative review".tw. or "integrative research review".tw. or "rapid review".tw. or "evidence based".ti. or "evidence based".ab. or (inclusion and criteri*).tw. or exclusion criteri*.tw. or handsearch.tw. or research synthesis.mp. or "realist synthesis".mp. or "realist review".mp. or "rapid realist review".mp. or "literature review".mp. or "narrative review".mp. or meta-ethnograph*.mp. or "narrative review".mp. or "narrative synthesis".mp. or "critical interpretive synthesis".mp. or "rapid review".mp. or "scoping review".mp. or "evidence synthesis".mp. or "research syntheses".mp. or "evidence review".mp. or "evidence map*".mp. or "systematic map*".mp.	2,266,105
2	limit 1 to yr="2005 -Current"	1,114,581
3	compensation.mp. or "Compensation and Redress"/	45,170
4	birth trauma.mp. or Birth Injuries/	5,208
5	(malpractice adj6 Obstetric*).af.	803
6	(payment adj6 Obstetric*).af.	16
7	(Litigation adj6 Obstetric*).af.	73
8	(scheme adj6 Obstetric).af.	11
9	3 or 4 or 5 or 6 or 7 or 8	51,123
10	limit 9 to yr="2005 -Current"	21,362
11	**2 and 10**	2,170

Coding tool

Type of study
CMO paper
Empirical data
No data
paper has been checked but no data to support CMO or to suggest a new CMO

Type of outcomes (tick all that apply)
JUSTICE 1: Access to courts
If claimants have access to the courts as well as the NFCS, there may be lower amounts of claims on the no-fault scheme as in France. If there is no access to the courts, there are higher rates of application to the schemes as in New Zealand and the Nordic countries (Barbot et al. 2014).
JUSTICE 2: Equality of access
Compensation entitlement levels impact on access to justice if greater sums can be gained through access to the courts – so only those wealthy enough to afford a lawsuit can pursue claims that may, if successful, lead to higher sums. However, the no-fault schemes ensure access to compensation no matter the income level of the applicant.
JUSTICE 3: Compensation decoupled from disciplinary procedures
Creating a Chinese wall between compensation procedures and disciplinary procedures enables speedier access to justice, since physicians are more ready to hand over the relevant information (Kachalia et al. 2008).
JUSTICE 4: Transparency of decision making
The transparency of the decision making process, including the use of expertise and precedent and easily applied criteria, increases the perception of fairness and improves access to justice.
CLINICAL PRACTICE: Defensive medicine
PATIENT SAFETY 1: Admitting to error
Anything that supports doctors to disclose injury or not; not individual liability but organisational/enterprise liability. Removing the stigma associated with negligence investigations and findings could make providers more comfortable discussing and admitting errors, in turn supporting learning and prevention.
PATIENT SAFETY 2: Learning from error
Anything that supports learning from error; databases capturing details of claims. Their effects on patient safety have not been systematically measured, but evidence suggests that system administrators make good use of their databases to identify safety problems and that they disseminate lessons learned nationally.
HEALTH 1: Improves physical health outcomes
NFCSs improve physical health outcomes.
HEALTH 2: Improves mental health outcomes
NFCSs improve mental health outcomes.
About birth
Anything relating to birth and compensation schemes.

Context: Type of compensation scheme / Focus of study
Details

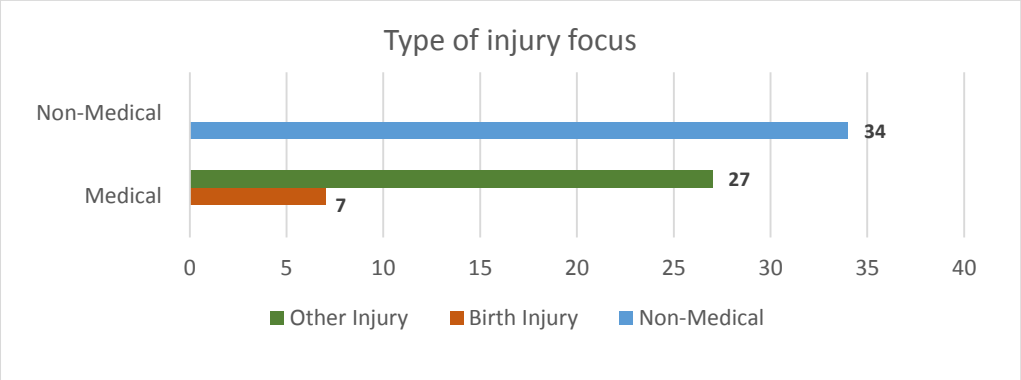
Type of injury
Medical
Non-medical

Appendix 3: Further details of papers included in the review

Brief overview of studies

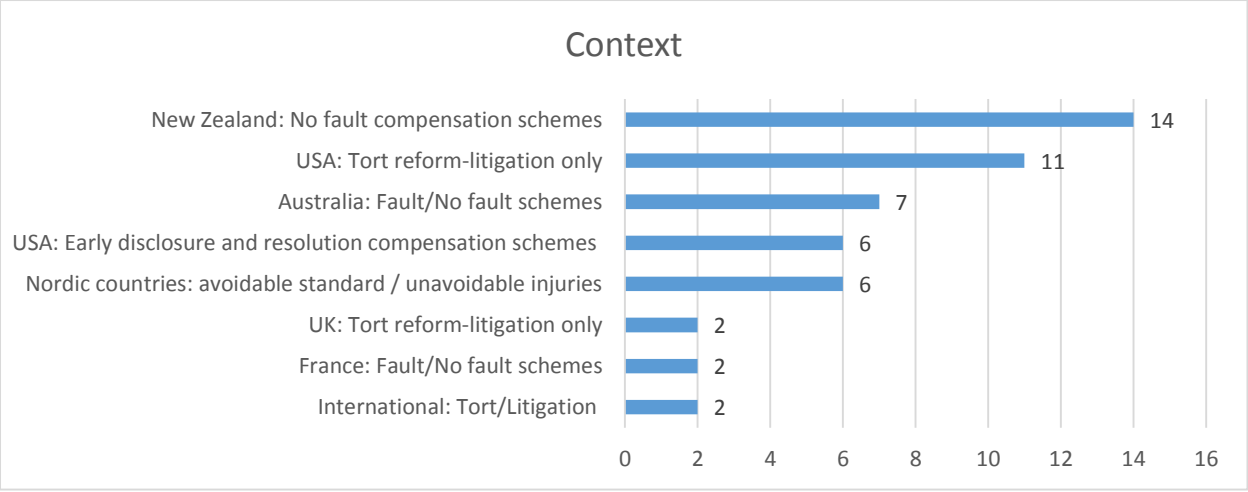
We developed the CMO framework by drawing on 44 papers, the majority of which were empirical studies (N=33). We specifically sought to identify papers pertaining to NFCSs for people who had experienced a birth-related injury. However, we found that the majority of studies on compensation schemes and tort reform focused primarily on medical injury (n=34) with only seven of these specifically related to the birth process. We included a further 10 studies on compensation schemes for people who had suffered injuries as a result of a transport-related or workplace accidents.

Figure A3.1: Injury focus



For the purposes of this realist review, context specifically relates to different compensation schemes or issues pertaining to tort reform in relation to the introduction of compensation schemes. A breakdown of the type and social and political systems within which schemes operate is provided in Figure A3.2. The 14 papers from New Zealand on NFCSs reflect the focus of this review and our search efforts. A further 11 papers focus on the USA and tort reform, specifically in relation to clinical practice outcomes and reducing defensive practice. We also identified papers on compensation schemes in Australia (n=7), the USA (n=6) and the Nordic countries (n=6). Few studies were identified from the UK (n=2) and France, although the latter might reflect an English language bias in the search.

Figure A3.2: Context



Note: Figures add up to more than 44 because some papers relate to more than one context.

Relevance appraisal

Judgements made about the relevance of the 44 papers included in the CMO configurations were assessed using the approach described in Chapter 6. The majority of papers (n=27) identified CMO configurations in relation to medical injury, and were therefore judged as of medium relevance. Only seven papers were specifically about compensating injury occurring during birth and were judged as of high relevance. The remaining ten studies were judged as low relevance (See Table A3.1), they were not excluded from the findings but are clearly signposted in the CMO framework to indicate their provisional usefulness to answering the review questions.

Table A3.3: Relevance judgements

Study relevance	N	Papers included in the CMO framework
High	**7**	Cheng et al. (2014); Dubay et al. (2001); Robertson and Thomson (2014); Sakala et al. (2013); Siegal et al. (2008); Yang et al. (2009); Yang et al. (2012)
Medium	**29**	Barbot et al. (2014); Bismark et al. (2006a); Bismark et al. (2006b); Bismark and Paterson (2006); Davis et al. (2002) Hugman (2007); Hyman et al. (2010); Jarvelin et al. (2012); Jena et al. (2015); Jonsson and Øvretveit (2008); Kachalia et al. (2008); Kachalia et al. (2016); Kessler (n.d.); Keren-Paz (2010); Malcolm and Barnett (2007); Mello et al. (2006); Mello et al. (2011); Murtagh et al. (2012); Montanera (2016); Pukk-Härenstam et al. (2008); Shurtz (2013); Sobrun-Maharaj et al. (2010); Vandersteegen et al. (2015); Wallis (2013); Wallis (2015); Wallis and Dovey (2011); Xu et al. (2013)
Low	**8**	Armstrong and Tess (2008); Cameron et al. (2008); Elbers et al (2013); Gabbe et al. (2007); Grant et al. (2014); Harrington (2015); Manson et al. (2015); Montgomery et al. (2015); Murgatroyd et al. (2015); Sterling et al. (2010);

Characteristics of papers

Table A3.4: Characteristics of papers included in the CMO Framework

Study	Injury focus	Context	Outcomes	Mechanism	Publication type and relevance
Armstrong and Tess (2008)	Non-medical *Work injury schemes*	**USA**: Early-disclosure and resolution schemes **New Zealand:** No-blame compensation schemes **Australia**: Fault/no-fault schemes	**Justice 2:** Equality of access	NFCSs that are ***free to access*** improve justice outcomes in that they are ***accessible to all eligible parties***, unlike the tort system which favours those who can afford legal representation.	**Publication type:** Non-systematic review **Relevance:** Low
Barbot et al. (2014)	Medical	**France:** Fault/no-fault schemes	**Justice 1:** Access to courts	To make compensation schemes attractive to claimants, they must ***offer payment*** **and** ***broader eligibility criteria***, to ensure schemes remain more appealing than the tort-based system.	**Publication type:** Policy review **Relevance:** Medium
			Justice 2: Equality of access	NFCSs that are ***free to access*** improve justice outcomes in that they are ***accessible to all eligible parties***, unlike the tort system, which favours those who can afford legal representation.	
			Justice 3: Transparency of process	Transparency of process achieves justice through the ***representation of the claimant*****,** and mechanisms that improve the ***consistency of decision making through the use of medical experts*** and the consideration of precedents.	

Study	Injury focus	Context	Outcomes	Mechanism	Publication type and relevance
Bismark et al. (2006a)	Medical	**New Zealand**: No-blame compensation schemes	**Justice 2:** Equality of access	NFCSs that are ***free to access*** improve justice outcomes in that they are ***accessible to all eligible parties***, unlike the tort system which favours those who can afford legal representation.	**Publication type:** Empirical study **Relevance:** Medium
			Justice 4: Compensation decoupled from disciplinary procedures	***Creating a 'Chinese wall' 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***.	
Bismark et al. (2006b)	Medical	**New Zealand**: No-blame compensation schemes	**Justice 2:** Equality of access	NFCSs that are ***free to access*** improve justice outcomes in that they are ***accessible to all eligible parties***, unlike the tort system which favours those who can afford legal representation.	**Publication type:** Empirical study **Relevance:** Medium
Bismark and Paterson (2006)	Medical	**New Zealand**: No-blame compensation schemes	**Patient safety 1:** Admitting to error	NFCSs 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***.	**Publication type:** Policy review **Relevance:** Medium:
			Patient safety 2: Learning from error	NFCSs 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***.	

Study	Injury focus	Context	Outcomes	Mechanism	Publication type and relevance
Cameron et al. (2008)	Non-medical *Traffic accidents*	**Australia**: Fault/no-fault schemes	**Health 1:** Physical health	NFCSs and tort reform improve the physical health of patients by ***shortening the length of time to claim closure*** and ***by including a rehabilitative element in the award***.	**Publication type:** Empirical study **Relevance:** Low
Cheng et al. (2014)	Medical *Birth-related*	**USA**: Tort reform only	**Clinical practice 1:** Defensive medicine	Tort reform and NFCSs ***reduce unnecessary tests and procedures*** and ***improve access to health care for patients considered 'riskier' by clinicians***, because doctors are less likely to practise positive and/or negative defensive medicine to protect themselves from litigation.	**Publication type:** Empirical study **Relevance:** High
Davis et al. (2002)	Medical	**New Zealand**: No-blame compensation schemes	**Justice 2:** Equality of access	NFCSs that are ***free to access*** improve justice outcomes in that they are ***accessible to all eligible parties***, unlike the tort system, which favours those who can afford legal representation.	**Publication type:** Empirical study **Relevance:** Medium
Dubay et al. (2001)	Medical *Birth-related*	**USA**: Tort reform only	**Clinical practice 1:** Defensive medicine	Tort reform and NFCSs ***reduce unnecessary tests and procedures*** and ***improve access to health care for patients considered 'riskier' by clinicians***, because doctors are less likely to practise positive and/or negative defensive medicine to protect themselves from litigation.	**Publication type:** Empirical study **Relevance:** High
Elbers et al (2013)	Non-medical *Traffic accidents*	**Netherlands**: Avoidable standard / unavoidable injuries	**Justice 3:** Transparency of process	Transparency of process achieves justice through the ***representation of the claimant***, and mechanisms that improve the ***consistency of decision making through the use of medical experts*** and the consideration of precedents.	**Publication type:** Empirical study **Relevance:** Low

Study	Injury focus	Context	Outcomes	Mechanism	Publication type and relevance
Gabbe et al. (2007)	Non-medical *Transport-related injuries*	**Australia**: Fault/no-fault schemes	**Health 2:** Mental health	NFCSs and tort reform improve the mental health of patients by ***shortening the length of time to claim closur***e and by ***removing the adversarial element of the tort system***.	**Publication type:** Empirical study **Relevance:** Low
Grant et al. (2014)	Non-medical *Transport and workplace injuries*	**Australia**: Fault/no-fault schemes	**Health 2:** Mental health	NFCSs and tort reform improve the mental health of patients by ***shortening the length of time to claim closur***e and by ***removing the adversarial element of the tort system***.	**Publication type:** Empirical study **Relevance:** Low
Harrington (2015)	Non-medical *Transport accidents*	**Australia**: Fault/no-fault schemes	**Health 1:** Physical health	NFCSs and tort reform improve the physical health of patients by ***shortening the length of time to claim closure*** and by ***including a rehabilitative element in the award***.	**Publication type:** Empirical study **Relevance:** Low
			Health 2: Mental health	NFCSs and tort reform improve the mental health of patients by ***shortening the length of time to claim closur***e and by ***removing the adversarial element of the tort system***.	
Hugman (2007)	Medical	**USA**: Tort reform only	**Clinical practice 1:** Defensive medicine	Tort reform and NFCSs ***reduce unnecessary tests and procedures*** and ***improve access to health care for patients considered 'riskier' by clinicians***, because doctors are less likely to practise positive and/or negative defensive medicine to protect themselves from litigation.	**Publication type:** Policy review **Relevance:** Medium

Study	Injury focus	Context	Outcomes	Mechanism	Publication type and relevance
Hyman et al. (2010)	Medical	**USA**: Tort reform only	**Patient safety 2:** Learning from error	NFCSs 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***.	**Publication type:** Empirical study **Relevance:** Medium
Jarvelin et al. (2012)	Medical	**Nordic countries**: Avoidable standard / unavoidable injuries	**Justice 2:** Equality of access	NFCSs that are ***free to access*** improve justice outcomes in that they are ***accessible to all eligible parties***, unlike the tort system which favours those who can afford legal representation.	**Publication type:** Empirical study **Relevance:** Medium
Jena et al. (2015)	Medical	**USA**: Tort reform only	**Clinical practice 1:** Defensive medicine	Tort reform and NFCSs ***reduce unnecessary tests and procedures*** and ***improve access to health care for patients considered 'riskier' by clinicians***, because doctors are less likely to practise positive and/or negative defensive medicine to protect themselves from litigation.	**Publication type:** Empirical study **Relevance:** Medium
Jonsson and Øvretveit **(2008)**	Medical	**Nordic countries**: Avoidable standard / unavoidable injuries *Sweden*	**Patient safety 2:** Learning from error	NFCSs 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***.	**Publication type:** Empirical study **Relevance:** Medium
Kachalia et al. (2008)	Medical	**Nordic countries**: Avoidable standard	**Justice 1:** Access to courts	To make compensation schemes attractive to claimants, they must ***offer payment*** **and** ***broader eligibility criteria***, to ensure	**Publication type:** Policy review

Study	Injury focus	Context	Outcomes	Mechanism	Publication type and relevance
		/ unavoidable injuries **New Zealand**: No-blame compensation schemes **International**: Tort/litigation		schemes remain more appealing than the tort-based system.	**Relevance:** Medium
			Justice 2: Equality of access	NFCSs that are ***free to access*** improve justice outcomes in that they are ***accessible to all eligible parties***, unlike the tort system, which favours those who can afford legal representation.	
			Justice 3: Transparency of process	Transparency of process achieves justice through the ***representation of the claimant***, and mechanisms that improve the ***consistency of decision making through the use of medical experts*** and the consideration of precedents.	
Kachalia et al. (2016)	Medical	**USA**: Early-disclosure and resolution schemes	**Patient safety 1:** Admitting to error	NFCSs 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***.	**Publication type:** Policy review **Relevance:** Medium
			Patient safety 2: Learning from error	NFCSs 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***.	

Study	Injury focus	Context	Outcomes	Mechanism	Publication type and relevance
Keren-Paz (2010)	Medical	**UK**: Tort reform only	**Clinical practice 1:** Defensive medicine	Tort reform and NFCSs ***reduce unnecessary tests and procedures*** and ***improve access to health care for patients considered 'riskier' by clinicians*****,** because doctors are less likely to practise positive and/or negative defensive medicine to protect themselves from litigation.	**Publication type:** Policy review **Relevance:** Medium
Kessler (n.d.)	Medical	**USA**: Tort reform only	**Clinical practice 1:** Defensive medicine	Tort reform and NFCSs ***reduce unnecessary tests and procedures*** and ***improve access to health care for patients considered 'riskier' by clinicians*****,** because doctors are less likely to practise positive and/or negative defensive medicine to protect themselves from litigation.	**Publication type:** Empirical study **Relevance:** Medium
Malcolm and Barnett (2007)	Medical	**New Zealand**: No-blame compensation schemes	**Justice 4:** Compensation decoupled from disciplinary procedures	***Creating a 'Chinese wall' 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***.	**Publication type:** Empirical study **Relevance:** Medium
Manson et al. (2015)	Non-medical *Work injuries*	**New Zealand**: No-blame compensation schemes	**Health 1:** Physical Health	NFCSs and tort reform improve the physical health of patients by ***shortening the length of time to claim closure*** and by ***including a rehabilitative element in the award***.	**Publication type:** Empirical study **Relevance:** Low
Mello et al. (2006)	Medical	**USA**: Early-disclosure and resolution schemes	**Patient safety 1:** Admitting to error	NFCSs 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***.	**Publication type:** Policy review **Relevance:** Medium

Study	Injury focus	Context	Outcomes	Mechanism	Publication type and relevance
			Patient safety 2: Learning from error	NFCSs 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***.	
Mello et al. (2011)	Medical	**USA**: Early-disclosure and resolution schemes	**Justice 4:** Compensation decoupled from disciplinary procedures	***Creating a 'Chinese wall' 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***.	**Publication type:** Policy review **Relevance:** Medium
Montanera (2016)	Medical	**International**: Tort/litigation	**Clinical practice 1:** Defensive medicine	Tort reform and NFCSs ***reduce unnecessary tests and procedures*** and ***improve access to health care for patients considered 'riskier' by clinicians***, because doctors are less likely to practise positive and/or negative defensive medicine to protect themselves from litigation.	**Publication type:** Empirical study **Relevance:** Medium
Montgomery et al. (2015)	Non-medical *Work injuries*	**New Zealand**: No-blame compensation schemes	**Health 1:** Physical health	NFCSs and tort reform improve the physical health of patients by ***shortening the length of time to claim closure*** and ***by including a rehabilitative element in the award***.	**Publication type:** Empirical study **Relevance:** Low
Murgatroyd et al. (2015)	Non-medical *Motor vehicle accidents*	**Australia**: Fault/no-fault schemes	**Health 1:** Physical health	NFCSs and tort reform improve the physical health of patients by ***shortening the length of time to claim closure*** and ***by including a rehabilitative element in the award***.	**Publication type:** Empirical study **Relevance:** Low

Study	Injury focus	Context	Outcomes	Mechanism	Publication type and relevance
Murtagh et al. (2012)	Medical	**USA**: Early-disclosure and resolution schemes	**Justice 3:** Transparency of process	Transparency of process achieves justice through the ***representation of the claimant***, and mechanisms that improve the ***consistency of decision making through the use of medical experts*** and the consideration of precedents.	**Publication type:** Empirical study **Relevance:** Medium
Pukk-Härenstam et al. (2008)	Medical	**Nordic countries**: Avoidable standard/ unavoidable injuries *Sweden*	**Patient safety 2:** Learning from error	NFCSs 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***.	**Publication type:** Empirical study **Relevance:** Medium
Robertson and Thomson (2014)	Medical *Birth-related*	**UK**: Tort reform only	**Clinical practice 1:** Defensive medicine	Tort reform and NFCSs ***reduce unnecessary tests and procedures*** and ***improve access to health care for patients considered 'riskier' by clinicians***, because doctors are less likely to practise positive and/or negative defensive medicine to protect themselves from litigation.	**Publication type:** Empirical study **Relevance:** High
Sakala et al. (2013)	Medical *Birth-related*	**USA**: Tort reform only	**Clinical practice 1:** Defensive medicine	Tort reform and NFCSs ***reduce unnecessary tests and procedures*** and ***improve access to health care for patients considered 'riskier' by clinicians***, because doctors are less likely to practise positive and/or negative defensive medicine to protect themselves from litigation.	**Publication type:** Policy review **Relevance:** High

Study	Injury focus	Context	Outcomes	Mechanism	Publication type and relevance
Shurtz (2013)	Medical	**USA**: Tort reform only	**Clinical practice 1:** Defensive medicine	Tort reform and NFCSs ***reduce unnecessary tests and procedures*** and ***improve access to health care for patients considered 'riskier' by clinicians*****,** because doctors are less likely to practise positive and/or negative defensive medicine to protect themselves from litigation.	**Publication type:** Empirical study **Relevance:** Medium
Siegal et al. (2008)	Medical *Birth-related*	**USA**: Early-disclosure and resolution schemes	**Justice 1:** Access to courts	To make compensation schemes attractive to claimants, they must ***offer payment*** **and** ***broader eligibility criteria*****,** to ensure schemes remain more appealing than the tort-based system.	**Publication type:** Policy review **Relevance:** High
			Justice 2: Equality of access	NFCSs that are ***free to access*** improve justice outcomes in that they are ***accessible to all eligible parties***, unlike the tort system which favours those who can afford legal representation.	
			Justice 3: Transparency of process	Transparency of process achieves justice through the ***representation of the claimant*****,** and mechanisms that improve the ***consistency of decision making through the use of medical experts*** and the consideration of precedents.	
Sobrun-Maharaj et al. (2010)	Medical	**New Zealand**: No-blame compensation schemes	**Justice 2:** Equality of access	NFCSs that are ***free to access*** improve justice outcomes in that they are ***accessible to all eligible parties***, unlike the tort system, which favours those who can afford legal representation.	**Publication type:** Empirical study **Relevance:** Medium
Sterling et al. (2010)	Non-medical	**Australia**: Fault/no-fault	**Health 1:** Physical Health	NFCSs and tort reform improve the physical health of patients by ***shortening the length of time to***	**Publication type:**

Study	Injury focus	Context	Outcomes	Mechanism	Publication type and relevance
	Traffic accidents	schemes		***claim closure*** and ***by including a rehabilitative element in the award***.	Empirical study **Relevance:** Low
Vandersteegen et al. (2015)	Medical	**Nordic countries**: avoidable standard / unavoidable injuries **France:** Fault/no-fault schemes **New Zealand**: No-blame compensation schemes	**Clinical practice 1:** Defensive medicine	Tort reform and NFCSs ***reduce unnecessary tests and procedures*** and ***improve access to health care for patients considered 'riskier' by clinicians***, because doctors are less likely to practise positive and/or negative defensive medicine to protect themselves from litigation.	**Publication type:** Empirical study **Relevance:** Medium
Wallis (2013)	Medical	**New Zealand**: No-blame compensation schemes	**Justice 4:** Compensation decoupled from disciplinary procedures	***Creating a 'Chinese wall' 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***.	**Publication type:** Policy review **Relevance:** Medium
			Patient safety 1: Admitting to error	NFCSs 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	NFCSs improve patient safety by enabling ***the pooling and sharing of information about medical errors*** and by ***reframing the compensation process as a patient safety***	

Study	Injury focus	Context	Outcomes	Mechanism	Publication type and relevance
				strategy rather than a risk management strategy.	
Wallis (2015)	Medical	**New Zealand**: No-blame compensation schemes	**Patient safety 2:** Learning from error	NFCSs 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***.	**Publication type:** Empirical study **Relevance:** Medium
Wallis and Dovey (2011)	Medical	**New Zealand**: No-blame compensation schemes	**Patient safety 1:** Admitting to error	NFCSs 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***.	**Publication type:** Empirical study **Relevance:** Medium
			Patient safety 2: Learning from error	NFCSs 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***.	
Xu et al. (2013)	Medical	**USA**: Tort reform only	**Clinical practice 1:** Defensive medicine	Tort reform and NFCSs ***reduce unnecessary tests and procedures*** and ***improve access to health care for patients considered 'riskier' by clinicians***, because doctors are less likely to practise positive and/or negative defensive medicine to protect themselves from litigation.	**Publication type:** Economic modelling **Relevance:** Medium
Yang et al. (2009)	Medical *Birth-related*	**USA:** Tort reform only	**Clinical practice 1:** Defensive medicine	Tort reform and NFCSs ***reduce unnecessary tests and procedures*** and ***improve access to health care for patients considered 'riskier' by clinicians***, because doctors are less likely to	**Publication type:** Empirical study

Study	Injury focus	Context	Outcomes	Mechanism	Publication type and relevance
				practise positive and/or negative defensive medicine to protect themselves from litigation.	**Relevance:** High
Yang et al. (2012)	Medical *Birth-related*	**USA**: Tort reform only	**Clinical practice 1:** Defensive medicine	Tort reform and NFCSs ***reduce unnecessary tests and procedures*** and ***improve access to health care for patients considered 'riskier' by clinicians***, because doctors are less likely to practise positive and/or negative defensive medicine to protect themselves from litigation.	**Publication type:** Empirical study **Relevance:** High
			Patient safety 1: Admitting to error	NFCSs 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***.	

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