Written evidence submitted by Patient Safety Learning (NLR0059)

Introduction

This submission sets out the response of Patient Safety Learning to the call for evidence for the Health and Social Care Select Committee Inquiry examining the case for the reform of NHS litigation.[1]

We are a charity and independent voice for improving patient safety. We harness the knowledge, insights, enthusiasm and commitment of health and social care organisations, professionals and patients for system-wide change and the reduction of avoidable harm. We believe patient safety is not just another priority; it is a core purpose of health and social care. Patient safety should not be negotiable.

Through our work we support safety improvement through policy, influencing and campaigning and the development of 'how to' resources such as *the hub*, our free award-winning platform to share learning for patient safety.

Submission summary

In our response to this Inquiry, we have chosen to focus on four key areas:

1. **Learning from avoidable harm in healthcare**

- Importance of shared learning for patient safety
- The role of NHS Resolution
- Clinical insights and recommendations from litigation cases
- Impact of the new Patient Safety Incident Response Framework

2. **Improving redress for patients**

- Independent Medicines and Medical Devices Safety Review
- Government position on an independent Redress Agency
- The need to reconsider redress

3. **The role of the Healthcare Safety Investigation Branch**

- Capacity for national investigations
- Implementation of recommendations

4. **Financial burden of avoidable harm and resulting litigation**

To conclude we outline the importance of considering NHS litigation reform as part of a wider context and the need for a transformation in our approach to patient safety. Key to this is patient safety being treated as core to the purpose of health and social care, not as one of several competing priorities to be traded off against each other.

1. Learning from avoidable harm in healthcare

Importance of shared learning for patient safety

[1] Health and Social Care Select Committee, NHS litigation reform, Last Accessed 18 October 2021. https://committees.parliament.uk/work/1518/nhs-litigation-reform/

Healthcare is systematically poor at learning from harm. Too often when effective solutions are found to prevent avoidable harm there is simply a lack of means by which we share these more widely. There is also a gap between learning and implementation; we often know what improves patient safety, but this information can remain siloed in specific organisations and health care systems, resulting in patients continuing to experience harm from problems that have already been addressed by others.

In our report, *A Blueprint for Action*, we set out what we believe is needed to progress towards a patient-safe future, identifying six foundations of safe care.[2] Sharing learning to improve patient safety is one of those six foundations. We make the case that for patients to be safer, we need people and organisations to share learning when they respond to incidents of avoidable harm, and when they develop good practice for making care safer. Patients, clinicians, managers, and health and social care system leaders should all be able to easily share learning about safety practice and performance.

The role of NHS Resolution

Serious incidents in healthcare can result in clinical negligence claims. There is a significant opportunity through these processes to understand what went wrong and the actions needed to prevent harm reoccurring. Such insights may often be applicable beyond the organisation in which the incident took place and provide a point for wider system learning.

NHS Resolution, the body responsible for providing expertise to the NHS on resolving concerns and disputes, acknowledges the importance of this and states that part of its organisation's purpose is to "share leaning for improvement and preserve resources for patient care".[3] Earlier this year it published with the Getting It Right First Time programme a joint guide to support learning from clinical negligence claims, and it publishes thematic reviews of specific areas of its work, such as *Learning from suicide-related claims* in 2018.[4] [5]

While such work is important and commendable, Patient Safety Learning believes that we are still missing significant opportunities to draw learning from the litigation process which can improve patient safety.

Clinical insights and recommendations from litigation cases

When clinicians are contacted as experts on litigation cases by a representative from the NHS Resolution 'Panel of Solicitors', as part of this process they are asked to feedback for any general points of learning to be shared across the NHS.

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[2] Patient Safety Learning, The Patient-Safe Future: A Blueprint For Action. Report, 2019. https://s3-eu-west-1.amazonaws.com/ddme-psl/content/A-Blueprint-for-Action-240619.pdf?mtime=20190701143409

[3] NHS Resolution, About NHS Resolution, Last Accessed 18 October 2021. https://resolution.nhs.uk/about/

[4] GIRFT and NHS Resolution, Learning from Litigation Claims, May 2021. https://www.gettingitrightfirsttime.co.uk/wp-content/uploads/2021/05/Best-practice-in-claims-learning-FINAL.pdf

[5] NHS Resolution, Learning from suicide-related claims: A thematic review of NHS Resolution data, September 2018. https://resolution.nhs.uk/wp-content/uploads/2018/09/NHS-Resolution_learing_from_suicide_claims_148pp_ONLINE1.pdf

While we believe that this is a valuable approach in principle, we have been disappointed to hear concerns from both clinicians and lawyers that their feedback has not been shared widely or acted on for improvement. We have contacted NHS Resolution about this process, who have said that the primary way these general points of learning are fed back into the system is:

- Through their members – these are shared with NHS Resolution member organisations on individual cases, which can be used to subsequently inform their own organisational clinical governance and patient safety processes.
- For wider learning – these inform NHS Resolution's in-depth reviews and studies on specific subject areas.

NHS Resolution have advised us that due to the nature of the information involved in clinical negligence cases, for a combination of privacy, personal sensitivity, and legal reasons they are limited in the ways they can share these insights for learning and improvement.

Patient Safety Learning believes that although there is clearly a degree of complexity involved with sharing such insights more widely, we are missing an enormous and valuable opportunity to extract significant system-wide learning that could improve patient safety. We believe that that insights from litigation could be used to inform regular publicly available reports which can help to:

- Share rapidly valuable information and opportunities for learning from litigation.
- Enable the Department of Health and Social Care, NHS England and Improvement, Care Quality Commission, Healthcare Safety Investigation Branch, the incoming Patient Safety Commissioner's in England and Scotland, and others to identify emerging patient safety trends/concerns.

We think there would be significant patient safety value in NHS Resolution collating these insights and sharing their findings publicly. We would suggest that as part of its inquiry, the Health and Social Care Committee should consider inviting NHS Resolution to outline why the causal factors of unsafe care identified through litigation cannot be shared more widely and what action can be taken to address this.

Impact of the new Patient Safety Incident Response Framework

Another area to consider concerning learning from avoidable harm in healthcare, and how this interacts with NHS litigation, is current NHS proposals to revise how organisations are expected to investigate error and harm through the new Patient Safety Incident Response Framework (PSIRF).[6]

There is much to be commended in the approach being proposed, such as ensuring that staff who undertake incident investigations are independent, properly trained and apply a human factors framework focused on learning and improvement. However, Patient Safety Learning is concerned that the implementation of this as currently proposed will result in far fewer investigations into serious harm. We believe that this will not only compromise opportunities for learning and improvement and could, in our opinion, frustrate patients and families.

This could also lead to the unintended consequence of an increase in complaints and even an increased chance of patients and families choose to pursue litigation in seeking to discover what happened in a patient safety incident. As with the clinical insights and recommendations from litigation cases discussed above, this is also another area where we believe there needs to be clearer

[6] NHS England and NHS Improvement, Patient Safety Incident Response Framework, Last Accessed 19 October 2021. https://www.england.nhs.uk/patient-safety/incident-response-framework/

mechanisms established to share learning from investigations between organisations and across the wider healthcare system.

2. Improving redress for patients

Independent Medicines and Medical Devices Safety (IMMDS) Review

Bound up with reform of NHS litigation is the issue of redress for avoidable harm in healthcare. This has recently been formally responded to by the Government, in response to the findings and recommendations of the IMMDS Review (also known as the Cumberlege Review).

The IMMDS Review examined the response of the healthcare system in England to the harmful side effects of three medical interventions: Hormone pregnancy tests, Sodium valproate and Pelvic mesh implants. It its report published in 2020, *First Do No Harm*, it made a number of recommendations to improve patient safety, including the creation of an independent Redress Agency for those harmed by medicines and medical devices.[7] It proposed that this should:

- Be set up on an avoidable harm basis, focused on systematic failings, rather than blaming individuals.
- Provide an approach to make decisions using a non-adversarial process, with a simple model of access for patients with one point of contact.
- Act as a collection point for litigation claims relating to avoidable harm, allowing this data to be collated and help inform regulators of emerging patient safety trends/concerns at an early stage.

Government position on an independent Redress Agency

The Government, in first its initial response to the IMMDS Review recommendations in January 2021, rejected this recommendation.[8] Subsequently its full response to the recommendations in July this year, it expanded on its rationale for this decision:

> *"We said in the Written Ministerial Statement of 11 January 2021 that the government has no current plans to establish a redress agency as set out in recommendation 3. We do not believe it is necessary to create a new agency for redress as it is already possible for the government and others to provide redress for specific issues where that is considered necessary (for example, the ex-gratia support through the Infected Blood Support Scheme). If, as the recommendation proposes, existing redress schemes were relocated behind a single front door of a new agency, we do not see that would necessarily improve patient's redress experience.*
>
> *Nor do we believe a redress agency in this country would necessarily make products safer or drive the right incentives for industry because many decisions by pharmaceutical and devices companies are made at a global level. Our primary focus as described throughout the government's response is on improving medicines and medical devices safety, setting high*

[7] The IMMDS Review, First Do No Harm, July 2020. https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf

[8] Department of Health and Social Care, Update on the Government's response to the Independent Medicines and Medical Devices Safety Review, 11 January 2021. https://www.gov.uk/government/speeches/update-on-the-governments-response-to-the-independent-medicines-and-medical-devices-safety-review?utm_medium=email&utm_campaign=govuk-notifications&utm_source=95beabd2-4856-484f-8bee-e3f450d1577a&utm_content=immediat

standards for industry to market and manufacture products, with the aim of reducing harm in the future. The UK has one of the safest medicines systems in the world and we will continue to make sure patients and the public have access to the best and most innovative medicines" [9]

Patient Safety Learning believes this response is unsatisfactory.

We believe that the Government should reconsider the proposals to establish an independent Redress Agency. Below we set out our thoughts on the two reasons quoted in the text above that it has provided for rejecting this proposal to date:

1. There is already an existing process in place where the Government can establish redress schemes for specific issues.

We believe the existing process is likely to create inconsistencies in how patients injured by avoidable harm are treated. It is particularly hard to see how such a system can be seen as fair when there is no publicly available rationale or criteria provided to clarify what issues are considered as appropriate for redress. In the case of the example provided of the Infected Blood Support Scheme, it has taken 40 years of campaigning before this has been eventually announced. It is hard to see how harmed patients can have confidence that the existing approach to considering decisions on redress is transparent, fair, consistent, or timely.

2. This would not make products safe or drive the right incentives for industry.

The IMMDS Review makes the case for an independent Redress Agency as improving patient safety by encouraging greater reporting and transparency, supported by a non-adversarial process which looks to systematic failings, rather than blaming individuals.[10] In its response the Government simply fails to engage with this point or argument in a meaningful way.

Moving away from their formal published response to the IMMDS Review, through representatives from the Department of Health and Social Care the Government also provided further comments on this as part of their response to the IMMDS Patient Reference Group, suggesting that providing redress to harmed patients would take funding away from patient safety improvement programmes.

We support the sentiment of IMMDS Patient Reference Group on this issue, with their formal report commenting:

"Many members of the group felt that the Government's position on previously established schemes providing redress was "wholly erroneous". Group members provided some evidence of the inaccuracy of this assertion and what patients need. The group want a clear definition of what is meant by 'redress schemes' when discussed by the policy team going forward.

Many expressed anger and insult as a result of "public money" being repeatedly mentioned as a barrier to redress and used the term "guilt trip" in response to this. Members also felt patronised by the response explanation. Members clarified that redress provide a place for

[9] Department of Health and Social Care, Government response to the Report of the Independent Medicines and Medical Devices Safety Review, 26 July 2021. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1005847/IMMDS_Review_-_Government_response_-_220721.pdf

[10] The IMMDS Review, First Do No Harm, July 2020. https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf

harmed individuals to recoup the costs caused by medical failings. One member highlighted "Evidence from schemes run outside the UK demonstrate that a dedicated medicines and medical devices redress agency does make products safer as it provides a central data collection point that can be monitored and responded to in a timely fashion. A no-fault redress agency also promotes an open, transparent and just culture across the NHS which further supports patient safety.""[11]

The need to reconsider redress

Patient Safety Learning believes that to improve the redress process the Government should reconsider its approach and engage more meaningfully with this proposal. We believe there are several issues it would be worth considering as part of this:

- Benefit to harmed patients in having a straightforward process and is accessible to all, equally.
- Potential for learning and identification of new and emerging issues because of having claims run through a centralised body.
- Potential benefits and drawbacks of introducing a no-fault compensation scheme.
- A cost-benefit analysis on the type of Redress Agency proposed, as opposed to the existing approach.
- How this may support a more open and supportive culture in relation to how NHS organisations respond to complaints and whether this may help to move away from a defensive response in some cases.

3. Role of the Healthcare Safety Investigation Branch

The Terms of Reference for this inquiry identify a specific issue for discussion around the work of the Healthcare Safety Investigation Branch (HSIB). It asks how HSIB can improve short term responses to patient safety incidents and therefore reduce the number of those who are forced to pursue litigation as a means of obtaining non-financial remedies.

Patient Safety Learning is strongly supportive of the role of HSIB investigations in identifying factors that have harmed or may harm patients, and their safety recommendations aimed at improving healthcare systems and processes. We believe there are however two significant issues which may limit their ability to reduce the number of incidents that lead to avoidable harm and thus reduce litigation:

1. Capacity for national investigations

HSIB is significantly limited by its capacity, currently it is only able to conduct up to 30 national investigations a year. This requires a significant degree of prioritisation against their investigation criteria, which means that for many issues where avoidable harm continues to occur, they will simply not have the capacity to investigate these areas and make safety recommendations.

2. Implementation of recommendations

[11] IMMDS Patient Reference Group, Independent Report of the Patient Reference Group – response to the report of the IMMDS Review, 21 July 2021. https://www.gov.uk/government/publications/the-independent-report-of-the-patient-reference-group-response-to-the-immds-review-report

When HSIB makes its safety recommendations, organisations are expected to respond within 90 days of publication of the investigation reports and HSIB subsequently shares these responses on their website.

However, while organisations are required to respond, there is no compulsion for them to accept or implement HSIB recommendations. Furthermore, there is no system of oversight to monitor or assess the effectiveness or impact of implementation. Without such a system, it is difficult to assess the impact of a safety recommendation in terms of preventing a recurrence of patient safety incidents that may result in harm and then future litigation.

4. Financial burden of avoidable harm and resulting litigation

In the UK, avoidable unsafe care kills and harms thousands of people each year, with the NHS stating that there are around 11,000 avoidable deaths annually due to safety concerns. This comes with an untold physical and emotional impact on those affected, a loss of trust in the healthcare systems and a loss of morale and frustration among healthcare professionals at not being able to provide the best possible care.

An often less discussed impact of unsafe care, particularly pertinent to litigation, is the huge financial cost that accompanies this:

- Unsafe care is forecast to cost the global economy approximately $383.7 billion by 2020.[12]
- The Organisation for Economic Co-operation and Development (OECD) estimate that the direct cost of treating patients who have been harmed during their care approaches 13% of health spending.[13]
- Excluding safety lapses that may not be preventable, this figure is considered to be 8.7% of health expenditure. This amounts to $606 billion a year, just over 1% of OECD countries combined economic output.[14]

The two diagrams on the next page, taken from the report *The Economics of Patient Safety. From analysis to action*, further illustrate the cost of unsafe care.

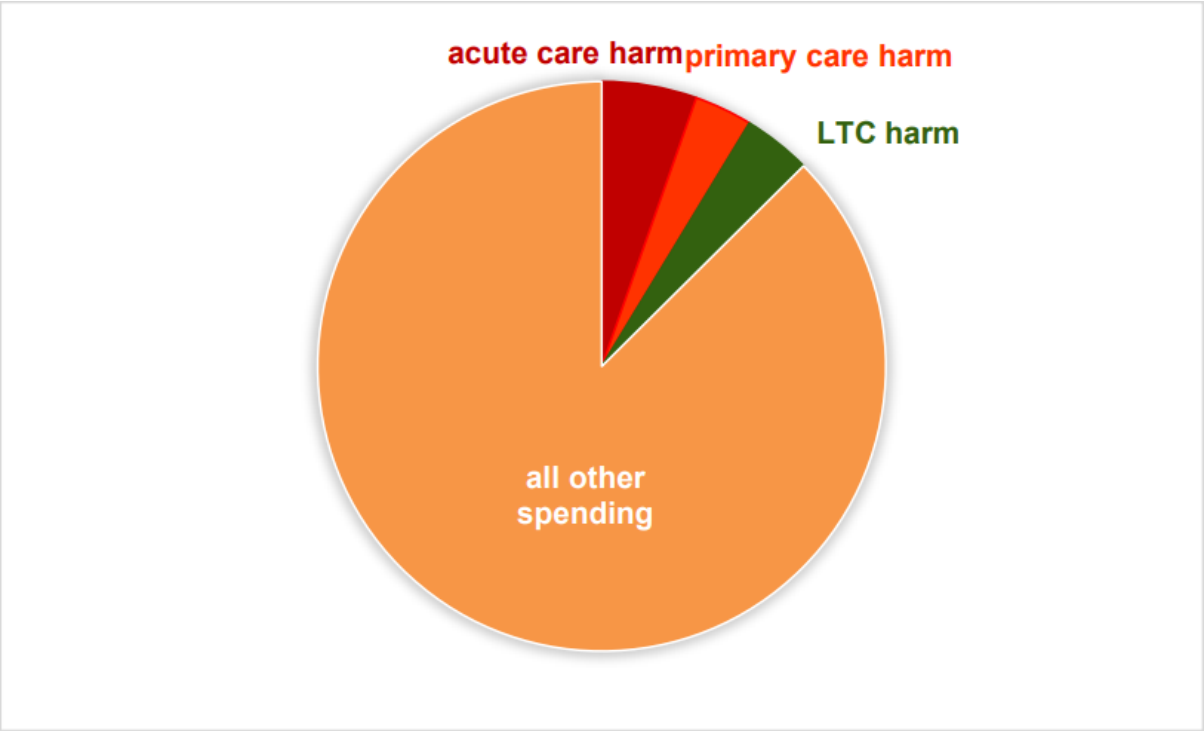
Figure 1: Treating the effects of unsafe care occupies a sizable proportion of health spending in OECD countries[15]

[12] The G20 Health and Development Partnership and RLDatix, The Overlooked Pandemic: How to transform patient safety and save healthcare systems, 25 March 2021. https://www.ssdhub.org/the-overlooked-pandemic/

[13] OECD, Patient Safety, Last Accessed 20 October 2021. https://www.oecd.org/health/patient-safety.htm

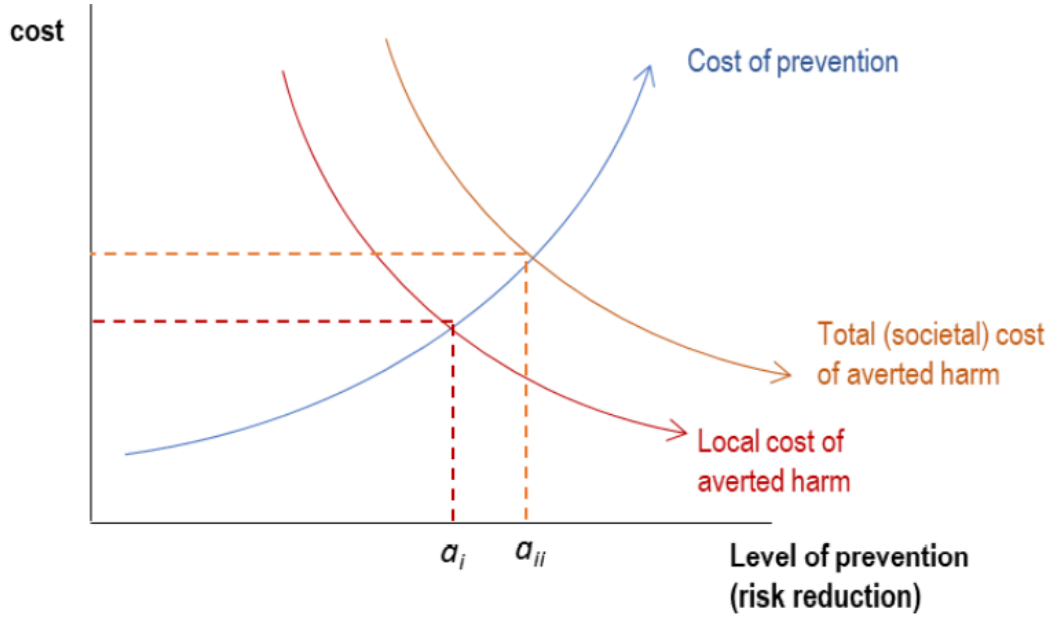
[14] OECD and Saudi Patient Safety Center, The Economics of Patient Safety. From analysis to action, 21 October 2020. https://www.oecd.org/health/health-systems/Economics-of-Patient-Safety-October-2020.pdf

[15] Ibid.



Source: Slawomirski et al (2017); Auraaen et al (2018); de Bienassis et al (2020)

Figure 2: Local costs of unsafe care do not reflect the total costs leading to sub-optimal investment in prevention[16]



Source: adapted from Zsifkovits et al (2016).

Turning specifically to the costs of NHS litigation, the costs of settling claims in 2020/21 came to £2.26 billion, with a further $7.9 billion spent on compensation claims settled in previous years.[17]

[16] Ibid.
[17] NHS Resolution, Annual report and accounts 2020/21, 15 July 2021. https://resolution.nhs.uk/wp-

Patient Safety Learning believes that the current costs of NHS litigation should be a clear signal to the Government that avoidable harm is not simply a serious health challenge, but also a major economic problem. While this remains unaddressed, scarce funds that could be spent to proactively improve the quality of care will instead be needed to deal with the cost of error and harm.

If we are to tackle the significant costs associated with this, we need to tackle the root cause of the problem. The most effective way to do this is to improve patient safety in healthcare, to reduce the level of avoidable harm, thus decreasing the associated costs of litigation, remedial support, and ongoing care. In our concluding comments, we set out what we think is required to do this.

Conclusion

In this submission we've set out our views on four areas related to the litigation process, learning from avoidable harm in healthcare, improving redress processes for patients, the role of HSIB and the financial burden of avoidable harm resulting in litigation.

These issues need to be considered as part of a wider context, acknowledging that the main causes of unsafe care are systemic. Avoidable harm in healthcare has complex roots and to make real progress we need to address these underlying system issues. We believe that there needs to be a transformation in our approach to tackling this problem. Key to this is patient safety being treated as core to the purpose of health and social care, not as one of several competing priorities to be traded off against each other.

In our report, *A Blueprint for Action*, we set out an evidence-based analysis of why harm is so persistent and what is needed to deliver a patient safe future, identifying six foundations of safe care:[18]

1) **Shared Learning** - organisations should set and deliver goals for learning, report on progress and share their insights widely for action.

2) **Leadership** - we emphasise the importance of overarching leadership and governance for patient safety.

3) **Professionalising patient safety** - recognising that organisational standards and accreditation for patient safety need to be developed and implemented. These need to be used by regulators to inform their assessment of safe care.

4) **Patient Engagement** - to ensure patients are valued and engaged in patient safety.

5) **Data and Insight** - better measurement and reporting of patient safety performance, both quantitative as well as qualitative.

6) **Just Culture** - all organisations should publish goals and deliver programmes to eliminate blame and fear, introduce, or deepen a Just Culture, and measure and report progress.

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content/uploads/2021/07/Annual-report-and-accounts-2020-2021-WEB-1.pdf

[18] Patient Safety Learning, The Patient-Safe Future: A Blueprint For Action. Report, 2019. https://s3-eu-west-1.amazonaws.com/ddme-psl/content/A-Blueprint-for-Action-240619.pdf?mtime=20190701143409

This change will require a transformation in our approach to patient safety, with reform to NHS litigation forming a key part of this.

Oct 2021