Patient Safety Commissioner
Listening to Patients

The Hughes Report

Options for redress for those harmed by valproate and pelvic mesh

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Contents

Foreword

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This report sets out my views on the options for providing redress for those harmed by pelvic mesh and the medicine valproate. Baroness Cumberlege's First Do No Harm review provided a detailed assessment of the healthcare and regulatory failures in both cases. It also made a series of important recommendations for government and the healthcare system to prevent similar harm reoccurring.

The purpose of my report is the next step – to explain what the government should do to meet the needs individual patients who have suffered "avoidable harm" because of these failures. Baroness Cumberlege rightly noted that after 'first do no harm' in the medical maxim comes 'and now do some good'.

My recommendations are designed to do this 'good' and provide the structure for the creation of a redress scheme covering pelvic mesh and valproate. I believe that the report can also function as a redress blueprint when approaching similar issues for those negatively impacted by medical devices and medicines in the future.

I want to acknowledge the campaigning by patients and their MPs that led to the Minister, Maria Caulfield, to ask me to take on this project in late 2022. When I agreed to do this work, I made two points to her.

First, the case for redress had already been made by the First Do No Harm review so my report would primarily focus on 'how' to provide redress rather than 'why'.

Secondly, patients must not be subjected to an emotional rollercoaster, meaning that commissioning this work would inevitably raise expectations and that it would be profoundly unfair to do so if the government had no intention of providing redress.

I want to thank all the patients who engaged with us during this process and whose voices are woven into the report. We have heard accounts of the immense suffering which they have experienced, physically, psychologically, socially and financially.

All those we spoke to have approached this process with openness and goodwill despite the considerable challenges they face. As time progresses, these challenges intensify and, understandably, there is now a growing sense of frustration and anger among patients. Confidence in the government to do the right thing is eroding.

Over the years, while these patients have been suffering, I have seen other healthcare scandals in this country rightly receive recognition and redress, from thalidomide to vCJD and, most recently, the infected blood scandal. Fairness demands that those harmed by valproate and pelvic mesh receive the recognition and redress to meet their needs.

The past cannot be changed. But the provision of redress gives the government an opportunity to demonstrate that the concerns of these patients have been heard, listened to and that their needs are being prioritised.

Finally, I would also like to express my thanks to my team who have listened and acted on the views and voices of patients and families with compassion and empathy. It is only by doing this have we been able to amplify patients' voices and needs to the heart of government.

Along with the patients, I eagerly anticipate the government's response.

Dr Henrietta Hughes
OBE FRCGP SFFMLM
Patient Safety Commissioner

Executive summary

This report is designed to help the government understand the options available for providing redress to those patients harmed by pelvic mesh and valproate. When agreeing to complete this work, the Patient Safety Commissioner made it clear to ministers that this report should lead to government action in this space. In support of this, we have made 10 recommendations to the government. The report has six chapters, with the first two providing important context to the later chapters.

The first point to make clear is that the Commissioner thinks that there is a clear case for redress based on the systemic healthcare and regulatory failures revealed by the First Do No Harm review in 2020. The Commissioner supports a restorative practice-based redress scheme, co-designed with affected patients, and which is, therefore, very different from court proceedings which seek to attribute blame. Chapter 1 also provides definitions for some key concepts that appear throughout the report.

Chapter 2 outlines developments since the publication of the First Do No Harm review in July 2020 to set out why, despite much positive work, redress is still required. The key development, from the point of view of this report, for both pelvic mesh and valproate is the government's rejection of Recommendation 3 (creation of an independent Redress Agency) and uncertainty around implementation of Recommendation 4 (creation of bespoke redress schemes) from the First Do No Harm review. This limbo is compounding patient harm.

Instead of implementing these recommendations, the government cites alternative work – such as the creation of two claim 'gateways' by NHS Resolution. However, these do not alter the underlying legal frameworks. As such, the gateways may not substantially benefit claimants particularly given the difficulties associated with litigation in this space.

Chapter 2 then goes on to discuss developments with valproate. The key theme in this section of the report is the overarching challenge with the implementation of the Medicines and Healthcare products Regulatory Agency's (MHRA) Pregnancy Prevention Programme for valproate – first introduced in 2018. The MHRA acknowledged and responded to these concerns with further updates in 2022 and 2023 – where it advised implementing further risk minimisation measures.

However, the Commissioner continues to have concerns about incomplete adherence to the Pregnancy Prevention Programme requirements. As a result, in November 2023, she recommended that NHS England create a fully funded and resourced system for improving the safe use of the most potent teratogenic medications, beginning with the safe use of valproate.

For pelvic mesh developments, we discuss the ongoing efforts to implement Recommendation 7 from the First Do No Harm review, calling for a medical device information system. We welcome the fact that NHS England started developing the Medical Device Outcome Registry in 2022, and that the APPRAISE study is developing a patient reported outcome measure. However, an audit on pelvic floor surgery, aimed at generating a historical baseline and supporting research, has faced data challenges, causing delays.

Finally, in terms of mesh, we acknowledge and welcome the fact that the specialist mesh centres have been established and are designed to support women managing mesh complications – implementing one half of Recommendation 5 of the First Do No Harm review. However, the patient survey conducted as part of this report found both satisfaction and dissatisfaction with the centres, suggesting further work is still required to improve patient outcomes.

Chapter 2 concludes by stating that the described developments, though positive, fall short of a comprehensive government-backed redress scheme for patients harmed by valproate and pelvic mesh. Crucially, no progress toward financial redress has been made. Concluding our review of these developments, we set out that a non-adversarial redress scheme covering both financial and non-financial aspects is urgently needed.

Chapter 3 moves on to explore patient experiences, including the physical, psychological and emotional impacts of the harm caused by valproate and pelvic mesh on patients and their families. It also highlights patients' daily struggles with accessing public services such as social security benefits and special educational needs support. We also discuss the challenges that patients face in seeking to get compensation and recognition via adversarial legal processes. Chapter 3 is crucial because we have built our recommendations in the later chapters on the needs of patients expressed in this chapter.

Chapters 4, 5 and 6 involve a more detailed discussion of what a redress scheme for those harmed by valproate and pelvic mesh should look like, and how many people may be eligible to access it. In places, we accept that it is technical – but have tried to break it down into different segments which come together to form the key elements of a redress scheme. We have also illustrated this concept by diagrams.

Chapter 4 begins with a discussion of what the non-financial elements of a redress scheme could look like. By 'non-financial', we refer to those changes that do not involve paying individual patients. We started on this topic because most of the patient survey respondents (over 90%) said that effective redress extends beyond financial compensation.

Our overarching proposal in this section on non-financial redress is that link workers should be employed to signpost patients to support, as well as offer an advocacy service. We also make suggestions in several specific areas where needs are greatest, as follows:

Area	Recommendation
Support for patient groups	These are an invaluable resource across many different areas for patients – but require support.
Housing	A dedicated housing support grant should be made available for harmed patients.
Healthcare	The specialist mesh centres require ongoing monitoring and improvement. For those harmed by valproate, a national specialist service should be established.
Social security	Improvements in the service that those harmed by valproate and pelvic mesh receive – including reduced frequency and intensity of reassessments.
Special educational needs support	National guidance to reduce the barriers harmed patients face in having their children's special educational needs (caused by valproate exposure) recognised due to a lack of awareness.
Apologies and acknowledgement	Consideration of how to issue individual apologies to those harmed.
Research and education	Funding for further research to understand pelvic mesh and anti-seizure medications.

Chapter 4 then discusses the headline issues relating to the financial elements of a redress scheme summarised in infographic 1.

This section starts with a discussion of what structure a redress scheme should adopt. On this topic, we recommend the creation of a two-stage scheme as set out in infographic 2B composed of an Interim Scheme and a Main Scheme.

The purpose of the Interim Scheme is to offer patients an initial, fixed sum in recognition of the avoidable harm they have suffered as a result of system-wide healthcare and regulatory failures. The Interim Scheme should be able to make payments to patients in 2025, so they do not have to wait long for some financial support. The results of the Interim Scheme will facilitate the government establishing the size of the harmed population where evidence is still sorely lacking before the launch of the Main Scheme.

The purpose of the Main Scheme is to recognise that the system-wide healthcare and regulatory failures caused different levels of harm to each patient. Consequently, the Main Scheme will require a more individualised approach with greater evidential requirements that will require more time to develop.

The chapter then moves onto a discussion of what sort of eligibility criteria would have to be in place to access redress through the Interim Scheme and the Main Scheme. An overview of these criteria is set out in infographic 3. We explain that eligibility will need to be restricted to those who fall within the definitions of directly and indirectly harmed – and we discuss our thoughts on how the government should define these two groups.

By 'directly harmed' we mean those individuals whose mothers were taking valproate at any point during their pregnancy, or those patients who were implanted with pelvic mesh to support pelvic organs for the treatment of stress urinary incontinence (SUI) or pelvic organ prolapse (POP). Those indirectly harmed includes those not directly impacted, but negatively affected – such as family members.

Based on these definitions, we suggest that only those directly harmed should be eligible for payment through the Interim Scheme. Those indirectly harmed could be provided for through the Main Scheme after further consultation and work on appropriate definitions.

Chapter 5 provides further information to the government on some of the operational issues involved in the creation of each of the two stages of the redress scheme. On some of these issues, the Patient Safety Commissioner has recommended how to proceed. In others, the Commissioner has decided to limit herself to a discussion of the issues, primarily because many of the details are contingent on decisions yet untaken by the government.

We start chapter 5 by stating that – in addition to meeting the overall eligibility criteria for the redress scheme discussed in chapter 4 – there will need to be a clear set of additional eligibility criteria specific to the Interim Scheme. These are set out in infographic 4.

We suggest, as a starting point, that these additional criteria will have to cover:

- cut-off dates for harm due to pelvic mesh and valproate, so that only patients who were harmed by treatment within specific dates should be eligible for an interim payment
- a 'qualifying injury' – which should be broadly defined via a multidisciplinary expert group for both pelvic mesh and valproate, drawing on international comparisons

When it comes to the sums to be paid to the harmed patients, the Commissioner wanted to amplify patients' views rather than endorse a specific figure – in line with her statutory remit and the scope of this project. The average (median) figure suggested by all patients who responded to our survey was £25,000 for the interim payment.

This discussion on the specifics of the Interim Scheme is then followed by a discussion on the specifics of the Main Scheme, and who should have access to it. We begin by making the point that those patients who receive an award from the Interim Scheme should not have to re-prove elements of their case to gain access to the Main Scheme. However, the individualised nature of the Main Scheme award will likely require additional evidence.

In addition, we argue that there is a strong case for a greater degree of discretion in proving eligibility for access to the Main Scheme. For example, discretion could be used to allow directly harmed patients entry into the Main Scheme who did not receive an interim payment because they could not meet the cut-off dates chosen by the government for the Interim Scheme – but who can demonstrate a compelling reason to be included.

Our section on the Main Scheme concludes by looking at the options that ministers will need to consider around the types of financial losses that the Main Scheme should cover. We go on to discuss the options relating to how the administrators of the Main Scheme should work out how much to pay patients in respect of each type of financial loss. This chapter summarises the pros and cons of each option but defers a final decision to the government once they have access to data from the Interim Scheme. As an overall summary, infographic 5 presents the proposed structure of the redress scheme.

We end chapter 5 by examining some important operational issues that span both the Interim Scheme and Main Scheme. The process for establishing eligibility through any redress scheme must not be onerous for the patient.

Any redress scheme will require an administrator. We describe how there are numerous options open to the government in this regard that are set out in the main body of the report. The Commissioner recommends that schemes are administered by an organisation which has the confidence of patients, and we do not believe that the Department of Health and Social Care (or a body sponsored by it) would command that support. Whatever administrator is chosen, they need to have a line of accountability to Parliament via the Public Accounts Select Committee given the public expenditure involved.

We then raise the important issue of capacity. As a result of the neurodevelopment disorders that are common with Fetal Valproate Spectrum Disorder (FVSD), the government will need to consider how to approach the potential that a sizeable proportion of those directly harmed will lack capacity. Chapter 5 also contains our recommendation that any scheme must be able to provide patients harmed through these two interventions with access to free emotional support regardless of whether they qualify or even wish to apply for payment.

On the funding of any redress scheme, we explain that there are three possible sources of funding for the redress scheme: the government, industry, or a combination of the two. We do not think it is appropriate for us to comment on this issue beyond this.

We conclude chapter 5 with our final recommendation – that a national communications campaign is needed to raise awareness of redress once launched, as a scheme is only worthwhile if people actually know about it.

Chapter 6 addresses the population harmed and the extent of harm, acknowledging challenges in estimating affected numbers due to inadequate data collection. It emphasises the importance of implementing the proposed Interim Scheme to produce better estimates.

After discussing the issues with the reported numbers of mesh procedures and reported complication rates, the Commissioner suggests that 10,000 patients may represent the lower end of those harmed by pelvic mesh, but she is unable to provide an upper estimate.

The number of children exposed to valproate in utero since its 1973 licensing is also difficult to estimate. However, the Commissioner makes a central estimate of around 14,000 for the period 1973 to 2017 in England only.

The government now has a responsibility not to disappoint the hopes of those harmed which they have raised by commissioning this report. By implementing a redress scheme built on the principles of restorative practice – as set out in this report – the government can seek to begin the process of putting right what has gone wrong.

List of recommendations

Recommendation 1

The government has a responsibility to create an ex-gratia redress scheme providing financial and non-financial redress for those harmed by valproate and pelvic mesh. This scheme should be based on the principles of restorative practice and be co-designed with harmed patients.

Recommendation 2

Redress should provide all those harmed by pelvic mesh or valproate with access to non-financial redress. To deliver this, the government should work with other government departments, the healthcare system and local authorities to measurably improve harmed patients access to, and experience of, public services.

Recommendation 3

The government should create a two-stage financial redress scheme comprising an Interim Scheme and a Main Scheme.

Recommendation 4

The Interim Scheme should award directly harmed patients a fixed sum by way of financial redress. These payments should start during 2025.

Recommendation 5

The Interim Scheme should be followed by a Main Scheme. This would offer more bespoke financial support to directly harmed patients based on their individual circumstances and – subject to further consultation on definitions – those indirectly harmed.

Recommendation 6

Patients who received relevant treatment through either the NHS or independent sector should be eligible for the Interim Scheme and Main Scheme.

Recommendation 7

Patients should find the application process for both the Interim Scheme and the Main Scheme straightforward, accessible and non-adversarial. To support this, a presumption of truth should be embedded within the scheme, which would apply when assessing the evidence provided by patients to meet the eligibility criteria.

Recommendation 8

Both the Interim Scheme and the Main Scheme should be administered by an independent body which commands the confidence of patients.

Recommendation 9

Both the Interim Scheme and the Main Scheme should effectively signpost harmed patients to services which can provide them with free emotional support.

Recommendation 10

The government must ensure that the launch of the Interim Scheme and the Main Scheme is accompanied by an awareness raising campaign to ensure that all potentially eligible patients are made aware of it. The government needs to make specific efforts to ensure those patients from disadvantaged and marginalised groups are reached.

Chapter 1:

Introduction

> "There is a sense of urgency. This was urgent 10 years ago."
>
> (Valproate advocate)

> "It always comes back to we innocently trusted that we were having something that was going to fix our embarrassing health condition and then from that we have had our lives shattered. This is not our fault."
>
> (Pelvic mesh harmed patient)

Summary

- The report should be read alongside the findings of the First Do No Harm review.
- We set out why we think that the case for redress for those harmed by pelvic mesh and valproate has been made out – and we call for government action.
- We define 'redress' and set out why it is so important that the redress provided is 'restorative.' This requires a focus on understanding and addressing the substantive, procedural and psychological justice needs of harmed patients.
- We set out our terms of reference and the remit of the Patient Safety Commissioner.
- We set out how we worked with our stakeholders.

1. The publication of the First Do No Harm review shone a light on a patient safety scandal that had been decades in the making but had largely been ignored.[1] This report covers two of the medical products and devices review – valproate and pelvic mesh. Terms which are defined in the glossary in annex B are in bold the first time that they appear in the main body of the report.

2. The report should be seen alongside the First Do No Harm review, which focused on what went wrong and why.[2] This report addresses how we repair the harm caused by the errors that were identified through the provision of redress, including financial redress for individuals.[3] Combined, the two reports provide a clear case for urgent government action.

3. The report builds on ministerial advice that the Commissioner submitted to the Department of Health and Social Care (DHSC) in October 2023. The report is split into the four areas covered by our terms of reference – the case for redress (across chapters 1, 2 and 3), what form and level of redress would be appropriate (chapters 4 and 5), and the size of the population harmed (chapter 6). Finally, the views of those harmed are covered in chapter 3, but also woven throughout the advice.[4] The full terms of reference agreed with DHSC are in annex C.

4. This report, and the earlier advice, are designed to help the government understand the options available when it comes to awarding redress to those patients harmed and, ultimately, to support government action.

5. In support of this report, we make 10 recommendations to the government. Implementation of these recommendations will support the government in launching the redress scheme in a timely manner for harmed patients.

6. When the Commissioner took on this work, she was clear that the government must avoid putting patients through an emotional rollercoaster by raising expectations, only to see them dashed again with further delays in agreeing to implement a redress scheme. We are hopeful that the government will heed this warning.

7. We are aware that it has taken years of work by campaigners and patients and in the case of valproate, decades to get to this point. We are under no illusion that another report is not, ultimately, what patients need. As one patient remarked to us, those harmed "needed redress yesterday". This report needs to mark the start of that action.

What do we mean by 'redress'?

8. Given the focus of this report is on 'redress', we want to start by defining what we mean when we use this term.

9. By redress, we mean a scheme of financial and non-financial support designed to help meet the needs of harmed patients.[5]

10. Redress respects the principles of **restorative practice**.[6] This is a term used to describe an approach which helps to build and maintain positive, healthy relationships, resolve difficulties and repair harm. The overriding questions that a restorative redress scheme must focus on answering must be 'who was harmed and what do they need to make things right for them?', followed by 'how can we learn from this and stop this from happening again?'

11. Therefore, effective and restorative redress must understand and address the needs of harmed patients. These needs can be broadly categorised into three types.[7]

Type of need	Definition
Substantive	The actual harms that need to be recognised and remedied.
Procedural	The process of communicating and making decisions about how to address harms. This would include the process of designing, launching, running and maintaining any redress scheme.
Psychological	The way people are acknowledged, respected and treated throughout the process.

12. A successful, restorative redress scheme would be co-designed with patients harmed by valproate and pelvic mesh, and those closest to them.

13. Redress can also be defined by what it is not. Redress is not a court mandated compensation award. The redress we envisage is more flexible and holistic and, crucially, can be made without attributing blame or liability (known as 'ex gratia').

Restorative practice

What is restorative practice and why do we think it is so important in remedying the harm that has occurred because of medical devices and medicines?

Restorative practice is a process where parties with a personal stake in an injustice collectively resolve how to deal with its aftermath and its broader implications for the future. Those harmed are empowered to enter a dialogue – with a view to ultimately reach agreement – about the best way forward for all those involved. These discussions must be facilitated within a safe and respectful environment.

The other important feature of restorative practice is that the outcomes of the process can be broadly defined. This means that the outcomes can cover what is required in terms of restoration of harm to those with a personal stake in the injustice.

Restorative practice can be contrasted with adversarialism, where two or more parties are required by a court – in a highly structured environment – to provide evidence to support their case and rebut the case of the opposing side. Additionally, a court is generally limited to an award of financial damages or costs at the end of the proceedings.

The restorative approach has a longer tradition within the area of criminal justice but is increasingly being used effectively in healthcare within England to repair harm – for example, in Mersey Care's Restorative Just and Learning Culture.[8] It also formed the heart of the 2019 New Zealand report into mesh harm, with authors stating that this restorative approach would "enable storytelling, provide validation and help to rebuild trust with harmed parties".[9] The Commissioner agrees – and believes that the restorative approach presents clear benefits to patients and all those involved in healthcare.

We have also sought to engage patients through this restorative lens. It was one of the reasons which led us to conclude that restorative redress involves more than the award of financial redress, but extends to non-financial redress, as set out at the start of chapter 4.

Why is redress required?

14. The past cannot be changed. But redress provides the government with an opportunity to demonstrate that the concerns of these patients have been heard, listened to and that their needs are being prioritised. For patients, a non-adversarial redress scheme presents a better – and for some, legally, the only – way to get recognition for what they have been through and support to move forward in their lives.

15. The patient experiences that the First Do No Harm review detailed, and which we have also heard and discuss, are harrowing. We, like Baroness Cumberlege, wish to acknowledge that those harmed by pelvic mesh and valproate are "almost universally women" – a defining feature of this harm when compared to other medical tragedies.[10]

16. The First Do No Harm review said that the harm inflicted was "avoidable", arising from systemic failings. This finding would have been injury enough. However, it has then been compounded over many years and decades, as patients' needs went unaddressed.

17. The government, as the body ultimately responsible for the system that failed patients, now has a unique responsibility to address this harm. It is right that the state offers a remedy for those who have suffered harm, through no fault of their own, because of a medicine or medical device, and where the state itself is ultimately responsible for the healthcare and regulatory systems that permitted the harm.

18. This, as a statement of principle, has an established history of being recognised and acted upon in this country – from thalidomide and vCJD through to infected blood most recently. In the context of infected blood, Sir Robert Francis KC recently put this principle as: "Where avoidable harm has been caused by a public service, albeit unintentionally, there is a moral case that those who are injured should receive redress."[11]

19. Such collective responsibility is what drove the foundation of the NHS itself:

> **"Illness is neither an indulgence for which people have to pay, nor an offence for which they should be penalised, but a misfortune the cost of which should be shared by the community."**[12]

20. With respect to pelvic mesh and valproate, the First Do No Harm review provides the necessary evidence of system-wide healthcare failures that caused avoidable harm to patients. It also found that harm arose from circumstances where patients were not provided with sufficient information to give informed consent to their treatment. This was because the healthcare and regulatory systems – for which the government is ultimately responsible – did not appropriately monitor risks and the possibility of long-term complications.

21. Overall, the healthcare and regulatory environment did not listen, respond, or react – as the then Secretary of State for Health and Social Care put it – "in the way I would expect in these three cases".[13]

22. We trust that none of the above is in dispute given that the government announced the First Do No Harm review on 21 February 2018 and then apologised after its publication on 8 July 2020, adding that "we need to take action".[14]

23. The case for redress has been made. For this apology to now become meaningful to patients, the 'action' that the government spoke of needs to include action on redress.[15]

Recommendation 1

The government has a responsibility to create an ex-gratia redress scheme providing financial and non-financial redress for those harmed by valproate and pelvic mesh. This scheme should be based on the principles of restorative practice and be co-designed with harmed patients.

The role of the Patient Safety Commissioner and terms of reference

24. The role of the Patient Safety Commissioner, as set out in legislation, is to promote the safety of patients and the views of patients in relation to medicines and medical devices in England.[16] Dr Henrietta Hughes OBE was appointed as the first Patient Safety Commissioner in September 2022.

25. The Patient Safety Commissioner was asked by DHSC ministers to undertake work on the options for redress for people harmed by valproate and pelvic mesh in late 2022. This was after a period of increased scrutiny of the government's action in this space by Parliament – including an adjournment debate on FVSD, and a Health and Social Care Select Committee hearing on the follow-up to the First Do No Harm review.[17, 18]

26. The Commissioner agreed terms of reference with DHSC in spring 2023. Work on the project began in summer 2023, after DHSC provided her with the required additional resourcing.[19]

27. Our terms of reference did not include the issue of hormone pregnancy tests. This was a decision taken by DHSC and should not be interpreted as representing the views of the Commissioner on the avoidable harm suffered in relation to hormone pregnancy tests or the action required to address this. The Patient Safety Commissioner wanted them included in the scope but, nevertheless, agreed to take on the work as defined by DHSC ministers.

28. We are confident that we have started the work required to understand and meet patients' needs within the confines of our terms of reference, resourcing and timeframes. However, we are also clear that the detailed implementation of any redress scheme by government will require considerably more and deeper engagement with patients and their representatives.

29. Finally, patients have been harmed by these two products across the UK. However, the Commissioner's statutory remit only extends to England.[20] In addition, health and healthcare services have been devolved matters since the start of the relevant devolution legislation – although the regulation of human medicines and medicinal products is a 'reserved' matter, meaning that this area remains the responsibility of the government on a UK-wide basis.[21]

30. Pelvic mesh products were first launched to the UK market in 1998.[22] This means that the vast majority of pelvic mesh was implanted after the start of the relevant devolution legislation. In contrast, valproate was first licensed for use in the UK market in 1973.[23]

31. It is not within the project's scope, nor the Commissioner's statutory responsibilities, to comment on these matters beyond the above. DHSC will need to engage with the devolved governments on these matters (as, for example, they have done with respect to redress for thalidomide survivors).

How we worked

32. The Patient Safety Commissioner worked alongside a small, internal project team to produce this work. The Commissioner agreed with DHSC on the appointment of Dr Sonia Macleod, Lead Researcher for the First Do No Harm review, as our expert advisor. In the interests of transparency, the declaration of interests for the Commissioner and Dr Sonia Macleod are in annex D – which first published on our website in September 2023.

33. Throughout the course of preparing the report, we held a number of meetings, both virtually and face-to-face, with patients and patient groups where we listened to their experiences of harm, views on redress and healthcare needs. These patients, who were often individuals representing large and diverse patient groups, have met us in good faith and in quiet dignity, despite the challenges that they face.

34. Alongside the meetings, we released an online survey which ran from 1 September to 13 October 2023 and received over 500 responses. A number of patients contacted us directly via email with their thoughts and insights. All these forms of patient engagement have helped to shape this report, and we start each chapter with a quote from someone harmed by, or with experience of, valproate and pelvic mesh.

35. We also met with a range of people from a medical, legal and academic background, as well as with Sanofi, the principal manufacturer of sodium valproate. We are extremely grateful to everyone who we met with for their time and expertise. A full list of those we met with is in annex F.

Chapter 2:

Where are we now? Recent developments in pelvic mesh and valproate

> "It's important for someone to take responsibility for what's happened to thousands of women whose lives have been ruined by this horrible mesh. Someone to say I'm sorry this has happened to you, but really mean it… I had this mesh put in my body at the age of 43 and was told it was the best thing since sliced bread. How wrong they were."
>
> (Pelvic mesh harmed patient)

> "Unfortunately, my son died due to his illness caused by valproate... I have been left a broken woman due to his loss… The children who are still living with this and their families deserve as much help as possible. We have to live every day feeling guilty for taking this medication [and] it's harder knowing it all could have been prevented."
>
> (Parent of valproate harmed patient)

Summary

- Chapter 2 provides an overview of developments in pelvic mesh and valproate since the publication of the First Do No Harm review in July 2020.
- The most important development for the purposes of this report – which spans both pelvic mesh and valproate – relates to the government's rejection of Recommendation 3 (the creation of an independent Redress Agency) and its uncertainty over Recommendation 4 (the creation of bespoke redress schemes) of the First Do No Harm review. This situation is unsustainable and is causing immense anxiety for harmed patients.
- In terms of valproate-specific developments, the overarching challenge has been with the implementation of the MHRA's Pregnancy Prevention Programme for valproate, which was first introduced in 2018. The Commissioner continues to have concerns in this area and , as a result, made a recommendation in November 2023 to NHS England.
- In terms of mesh-specific developments, work is underway to implement Recommendation 7 of the First Do No Harm review in terms of NHS England's Outcomes and Registries Programme. However, the planned audit on pelvic floor surgery, which aimed to establish outcome baselines, has encountered data challenges that have delayed publication.
- We also welcome that the specialist mesh centres, proposed by Recommendation 5 of the First Do No Harm review, have been established. However, our survey results on patient experiences with these centres were mixed, reflecting both satisfaction and dissatisfaction.
- Overall, these developments, though positive, fall short of a comprehensive government-backed redress scheme for patients harmed by valproate and pelvic mesh. A non-adversarial redress scheme covering both financial and non-financial aspects is urgently needed.

General developments spanning valproate and pelvic mesh

36. This section examines the period between the publication of the First Do No Harm review in July 2020 and the finalisation of this report. The Patient Safety Commissioner made valproate and pelvic mesh two of the three priorities for her first year in post and has been following developments closely.[24] The report provides a timely opportunity for her to comment on developments, as she looks to broaden her strategic focus for the remainder of her first term.

37. The First Do No Harm review made a number of recommendations designed "to make the system safer in the future". Implementation of those recommendations and of related safety improvements should be seen as part of redress.[25]

38. Since July 2020, there has been considerable progress in how the healthcare system and government approach pelvic mesh and valproate, and we wish to publicly acknowledge this progress.

The First Do No Harm review – a progress update

39. The First Do No Harm review made nine overarching recommendations, supported by a larger number of actions for improvement.[26]

40. The First Do No Harm review team kindly shared with us their appraisal of progress against these nine recommendations, as at spring 2023.[27] This update marks two of the nine recommendations as implemented, two as not implemented, and five as progress made – but with further work to do.

41. Recommendations 1 (a government apology) and 2 (appointment of a Patient Safety Commissioner) were judged to have been implemented.

42. On Recommendation 1, the Secretary of State for Health and Social Care gave an apology on the day of the publication, as did the then minister responsible for patient safety when introducing First Do No Harm to the House of Commons.[28, 29] The then Lords Health Minister Lord Bethell did the same when introducing the report to the House of Lords.[30]

43. On Recommendation 2, the Medicines and Medical Devices Act 2021, Section 1, established the Commissioner for Patient Safety.[31] Further details were set out in secondary legislation in 2022.[32]

44. The other two recommendations most relevant to the issue of redress, and this report, are Recommendation 3 (a new independent Redress Agency) and Recommendation 4 (bespoke redress scheme for each intervention, hormone pregnancy tests, valproate and pelvic mesh). Recommendation 3 was marked as not implemented and Recommendation 4 as progress made as a result of the government commissioning the Patient Safety Commissioner to complete this piece of work.

45. In relation to Recommendation 3, the government has repeatedly rejected the call for establishing a new independent Redress Agency for those harmed by medicines and medical devices.[33] Since these statements, we are not aware of any work towards establishing an umbrella-style independent Redress Agency with a broad remit to provide redress to those harmed by any future medicines or medical devices.

46. The government has appeared to be more uncertain on the implementation of Recommendation 4 and the creation of bespoke schemes, which has led to increased anxiety for harmed patients.

47. For example, in January 2021, the government stated that Recommendation 4 remained "under consideration".[34] Discussions continued throughout 2021 and 2022. The All-Party Parliamentary Group for First Do No Harm wrote to the Minister for Mental Health and Women's Health Strategy, Maria Caulfield MP, on 18 May 2022, advocating for the implementation of Recommendation 4.[35] The response to this letter stated that the government was considering such redress schemes.[36]

48. It was against this backdrop that Maria Caulfield first asked the Patient Safety Commissioner to undertake this work into options for redress in late 2022, as described above.

49. In agreeing to complete this work, the Patient Safety Commissioner agrees with the First Do No Harm review that the government's current rejection of Recommendation 3 does not, and should not, prevent granting redress for those harmed by valproate and pelvic mesh. And, despite the government's continued rejection of Recommendation 3, we endorse First Do No Harm's statement that any bespoke schemes created for pelvic mesh and valproate should "be structured so that they can be incorporated into the wider Redress Agency in due course".[37]

NHS Resolution new claim pathways

50. In place of substantive progress on a redress scheme for pelvic mesh and valproate, the government has frequently championed the creation of two claims gateways on NHS Resolution's website to provide further support to patients who may wish to bring a clinical negligence claim for either intervention.[38]

51. Each of these gateways has a dedicated webpage on NHS Resolution's website with information for patients, template resources (including a template letter of claim) and a dedicated point of contact mailbox.[39] For patients who do not want to go down the formal litigation route, the webpages also set out an alternative procedure whereby claims can be assessed by solicitors acting on behalf of NHS Resolution. If the solicitor concludes that the legal test for clinical negligence is met, an offer may be made without the need for an order from the court.

52. In April 2023, the government reported that NHS Resolution had received 16 new claims through these gateways, although it was too early for any of them to result in compensation being paid.[40]

53. We welcome the provision of greater information to patients on their legal options, including the creation of template resources which may support those without access to legal representation.

54. However, we think that the term 'claims gateway' is misleading. It suggests that the government has created new, easier legal frameworks or routes to litigation. This is not the case, as the government itself acknowledges.[41] For example, these gateways do not change the limitation periods that can pose such difficulties for claimants.[42] This is particularly the case for valproate and mesh where the injuries may not be immediately apparent to patients, generating legal uncertainty as to when the 'clock starts' on the relevant limitation period. We also note that NHS Resolution is not independent from the claims that it is assessing. However, NHS Resolution has indicated to us that it takes a flexible approach to limitation issues in mesh and valproate claims, recognising the difficulties faced by claimants in some individual cases.

55. Overall, we do not think that it is appropriate for the government to point to this work as an example of how it is progressing the cause of redress for patients. It completely overlooks the experiences of patients detailed in chapter 3 who have struggled with the traditional, adversarial legal processes.

56. Therefore, we agree with the Health and Social Care Select Committee that these gateways "do not provide a substantial change nor benefit to those seeking to bring claims".[43]

Legal cases and settlements

57. We have stated above that we think that a redress scheme provides a better route to justice for patients. However, we think that it is important to provide a brief update to Appendix 3 of the First Do No Harm review, which provided an overview of litigation efforts for pelvic mesh and valproate.[44] This is particularly because some may wish to argue that a redress scheme is not needed given the viability of litigation.

58. Since 2020, there has been little progress through litigation in relation to harm from valproate or pelvic mesh in England.[45] From our patient engagement and media reports, we are aware of some pelvic mesh patients who have taken individual litigation cases and reached either an out-of-court settlement or been awarded damages. We also understand that these cases have largely been based on clinical negligence, as opposed to product liability.[46]

59. However, for various reasons (both procedural and substantive), it seems unlikely for either product that we will see large-scale group action in England resulting in any significant settlement for distribution among harmed patients. England and Wales are different legal jurisdictions to the other countries referenced below, where patients have had some success – and legal and procedural rules differ. This means that the successful outcome in one jurisdiction (with one class of claimant) may not translate into success in this jurisdiction. For example, settlements were reached in the USA and Australia concerning the adverse effects associated with the COX-2 selective inhibitor rofecoxib (marketed under the brand name Vioxx), but not in England and Wales.[47]

60. Although a detailed examination of the potential reasons for these differences is outside the scope of this report, we frequently heard from solicitors representing patients that England and Wales is not, on objective measures, a claimant-friendly jurisdictions when compared with other parts of the world.

61. In terms of other jurisdictions, it was reported in June 2020 that Johnson and Johnson agreed to pay an undisclosed sum to settle a legal action by hundreds of Scottish women who claimed they suffered serious injuries from the company's pelvic mesh implants.[48] In Australia, a class (or representative) action in relation to pelvic mesh was successful in 2019, with an appeal against this judgement dismissed in 2021.[49, 50]

62. However, while representing a success for claimants, the Australian pelvic mesh case is also a very good example of the immense difficulties, costs and time involved in bringing a legal case in this space. The case involved a 7-month trial with 48 witnesses and more than 5,000 documents consisting of over 164,000 pages.[51]

63. On the valproate side, there are reports of developments in Ireland with regards to clinical negligence.[52] In addition, the Irish Government announced the launch of a non-statutory inquiry into the historical licensing and use of valproate in women of child-bearing potential in June 2023.[53] Generally, legal proceedings appear most advanced in France, with successful first-instance verdicts in a class action, as well as an action brought by an individual family, against Sanofi.[54]

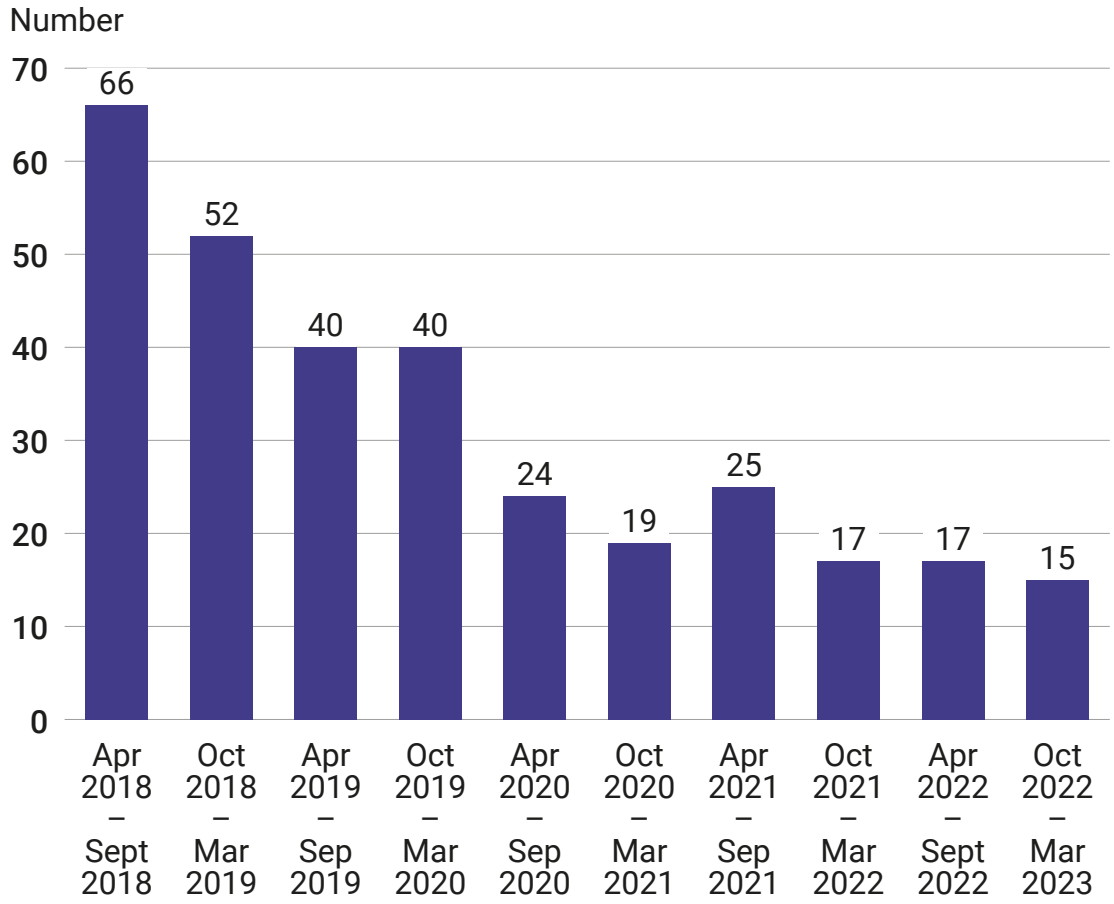
Specific developments with regards to valproate

64. The MHRA is working in partnership with NHS Digital (which merged with NHS England in 2023) to develop a comprehensive national Medicines in Pregnancy Registry on valproate use in females aged 0 to 54 in England.[55] The data goes back as far as 1 April 2018, and reports continue to be published twice yearly, with a 6-month lag on the data.[56]

65. The latest report published in September 2023 (covering the period from April 2018 to March 2023) showed that, overall, 18,235 female patients in this age group were prescribed valproate in the month of March 2023, down from 27,441 females in April 2018 – a 33% decrease.[57] This is welcome.

66. However, underneath this overall decrease there remains some worrying information. For example, 315 females on the register have been prescribed valproate during their pregnancy since April 2018. The growth of this cumulative total and change every six months is shown in figure 1 (data is correct as of December 2023), with the caveats noted in the endnotes.[58]

Figure 1: Number of females prescribed valproate during pregnancy within a 6-month period



Source: NHS Medicines and Pregnancy Registry. Available at: **https://tabanalytics.data.england.nhs.uk/t/Public/views/MedsPreg/TitlePage**

67. Most concerning of all is that, of these 315 patients, 30 are classed as 'new starters' during the pregnancy. This means that these patients were prescribed valproate within their pregnancy period but were not prescribed valproate within the previous 12 months.

68. We agree that valproate is an effective medication for the treatment of epilepsy and bipolar disorder. But to be used safely, the healthcare system must place patients in a position where they can weigh up the risks and benefits of the medication and can, therefore, provide informed consent. Our concern is that the gaps in the system of protection mean that this still does not happen with respect to every patient.

69. In addition, gaps in the data remain. One largely unexplored area of concern that we have is the wide variation in valproate dispensing in different parts of England. Recent research illustrates these differences and supports the more anecdotal evidence that we also heard on this issue.[59]

The implementation and monitoring of the Pregnancy Prevention Programme

70. The MHRA regulates medicines and medical devices in the UK. Its primary regulatory focus is to ensure that medicines and health products available in the UK are safe and effective.[60]

71. As reported by the First Do No Harm review, the MHRA introduced further restrictions in its Drug Safety Update 2018.[61] A crucial part of the MHRA recommendations were that:

- valproate must not be used in pregnancy (unless there is no suitable alternative treatment and clear information has been provided and understood by the patient regarding the risks)
- women of childbearing potential should have in place a pregnancy prevention programme if prescribed valproate

72. The Pregnancy Prevention Programme is a system of ensuring all women of childbearing potential taking valproate medicines:

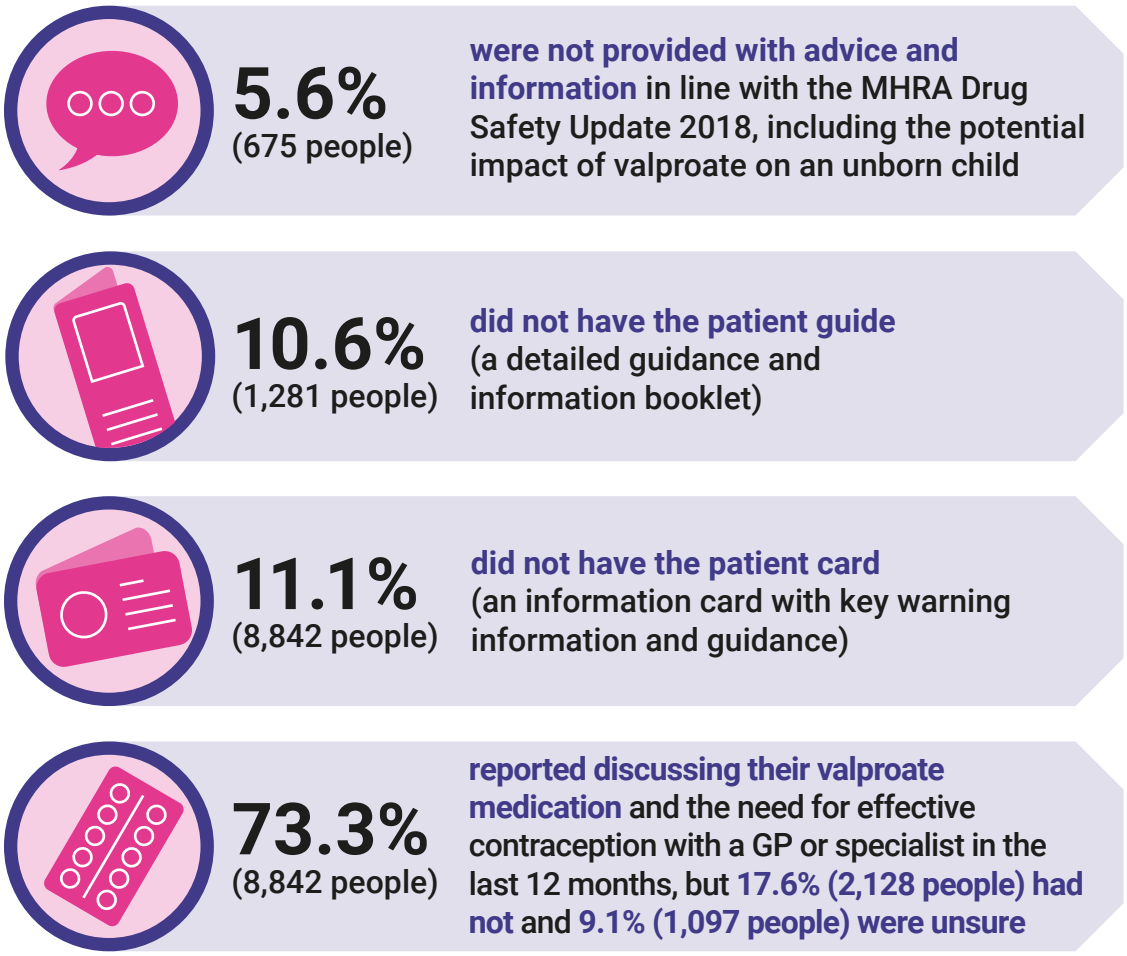
- have been told and understand the risks of use in pregnancy and have signed a Risk Acknowledgement Form, followed up by the ongoing requirement of an Annual Risk Acknowledgement Form
- are on highly effective contraception, if necessary
- have at least an annual review with their specialist

73. While this update was published in 2018, compliance in the immediate aftermath appeared patchy. The publication of the First Do No Harm review brought a renewed focus from the MHRA, NHS England and healthcare providers on ensuring that these requirements were being consistently applied.

74. NHS England sent a letter in June 2021 to patients with childbearing potential aged 12 to 55 who were currently prescribed valproate, which contained a reminder of safety considerations on contraception, pregnancy and regular prescribing reviews.[62]

75. However, worrying evidence continued to emerge. For example, NHS England's 'Community Pharmacy Quality Scheme: 2019/20 Valproate Audit Report', published in August 2022, presented a mixed picture on compliance with the full requirements of the Pregnancy Prevention Programmeas illustrated by the graphic below.[63]

Out of the 12,068 patients or patient representatives who agreed to take part in the audit:



76. A major update on the guidance was published by the MHRA (after advice from the Independent Commission on Human Medicines) in December 2022. In this update, the MHRA acknowledged "concerns that the current regulatory requirements for safe use are not being consistently followed".[64]

77. In this update, the MHRA advised further risk minimisation measures were required, in particular:

- no one under the age of 55 should be initiated on valproate unless two specialists independently consider and document that there is no other effective or tolerated treatment
- where possible, existing patients should be switched to another treatment unless two specialists independently consider and document that there is no other effective or tolerated treatment or the risks do not apply[65]

78. Other measures recommended by the MHRA included further warnings in the product information, improved educational materials, and better monitoring of healthcare professionals' compliance with the new measures.[66] The MHRA said that these new measures would be implemented over the coming months.[67]

79. NHS England published a decision support tool in May 2023 to help patients understand the risks and benefits of valproate and support them to start or continue taking it.[68] In November 2023, the MHRA published a National Patient Safety Alert setting out the Independent Commission on Human Medicines' advice on additional measures required to reduce the serious harms from valproate. It asks the healthcare system across the UK to develop an action and improvement plan to implement these measures by 31 January 2024.[69]

80. However, concerns remain. A key piece of evidence to assess the effectiveness of these efforts will be the follow-up to the 2019/20 Valproate Audit.[70] Pharmacy participants had to finish their data collection for this 2022/23 Valproate Audit by 31 March 2023.[71] Unfortunately, the results have not yet been published and NHS England told us that it does not currently have a timeline for publication.

Original packaging consultation

81. As discussed above, one of the key failures identified by the First Do No Harm review across both pelvic mesh and valproate was a failure of informed consent.[72] Too often, patients were not told of the risks associated with the medicines that they were being prescribed, or the devices that were being implanted into them.

82. As a result, much work has been undertaken to improve the outer labelling of boxes of valproate and the Patient Information Leaflets contained within them. However, worrying issues persist.

83. For example, on her second day in post in September 2022, a patient sent the Commissioner a photo of valproate dispensed in a plain white box. This box had none of the specific and unique warning and pictograms that are now on the original packaging produced by the manufacturers, as required by the MHRA to support the Pregnancy Prevention Programme.

84. This problem of plain packaging had already been recognised by DHSC and the MHRA. They ran a consultation on original pack dispensing of medicines containing valproate in community pharmacies across the UK between 1 November and 13 December 2021.[73] However, by the time the Commissioner started in post in September 2022, progress on a response to this consultation appeared to have stalled.

85. After the Commissioner made representations to DHSC and the minister on the importance of these issues, DHSC published the outcome to the consultation in March 2023.[74] In this document, DHSC and the MHRA agreed to introduce the necessary legislative amendments to implement the proposals on valproate, subject to protections for vulnerable patients.[75]

86. The Commissioner continued to press the government on a timetable for implementation and was pleased to see that the necessary secondary legislation required to change the law came into force on 11 October 2023.[76]

Specialist valproate centres

87. Recommendation 5 of the First Do No Harm review stated that:

> **"Networks of specialist centres should be set up to provide comprehensive treatment, care and advice for those affected by implanted mesh; and separately for those adversely affected by medications taken during pregnancy."**

88. While this recommendation was quickly picked up by NHS England in relation to pelvic mesh, progress has been slower with centres for medications taken during pregnancy. The government originally rejected this recommendation, arguing that:

> **"The establishment of a new network of specialist centres specifically focused on those affected by medicines in pregnancy is not viewed as the most effective way forward."**[77]

89. We disagree. As we explain in chapters 3 and 4, without these 'one stop shops', valproate harmed patients and their families have been left with an inconsistent patchwork of services and have struggled to get a proper diagnosis.

90. Therefore, we were pleased to see that in autumn 2023, NHS England announced work to develop and test a model of multi-agency working to support patients exposed to valproate. This model will operate as a 'hub and spoke' project in 2024 and is being run in conjunction with the Newcastle and Manchester NHS Foundation Trusts.

91. The hub will work with the relevant local 'spoke' services, which will deliver the treatment plan recommended by the hub service. The 'spoke' services include both health services, including genetic and mental health services and broader services such as educational services, family support services and third sector services.

92. The pilot will inform the development of a proposal for a national hub and spoke model to ensure that patients exposed to valproate will have access to expert diagnosis, treatment plans and a range of physical, psychological, social and educational support.

Overall – valproate

93. The above overview presents a mixed picture with regards to improvements in the safe use of valproate. In addition, the Commissioner has heard and seen many accounts of related issues with the safe and effective prescribing of valproate – many of which are broader than the topics discussed above.[78]

94. These issues are wide-ranging and have included:

- women starting on valproate when already pregnant
- variation in levels of valproate prescribing in different parts of England
- patients not receiving full information about the risks of valproate to the foetus
- the Annual Risk Acknowledgement Form being sent to patients by post with a stamped addressed envelope, with 50% returned
- lack of staff trained to advise and fit highly effective contraception in specialist hospital clinics – patients are directed to make their own contraceptive arrangements either through their GP or community contraception clinics
- inconsistencies between the MHRA definition of 'highly effective' contraception for women on valproate and NHS England's decision support tool
- the arrangements for commissioning of contraception through local authorities acting as a barrier to accessing contraception in hospital clinics
- the current Annual Risk Acknowledgement Form not including the type of contraception used, so it is not clear to the GP or pharmacist if it meets the definition of highly effective contraception, which is required to prescribe valproate under the Pregnancy Prevention Programme
- contraceptive clinics not requiring a referral, and no systems to inform secondary care or the GP of the details of contraception or for the clinic to know about the patient's anti-epileptic medication – equally, if the implant is removed at a contraceptive clinic, this update is not registered on the GP system
- patients not all having annual reviews – some have been lost to follow-up by their neurologist or psychiatrist

- patients getting their prescriptions for valproate from their GP and not being aware of gaps in information flows – they assume that all their professionals are keeping in touch
- the GP prescribing valproate on behalf of secondary care must tick a box that the annual review and Annual Risk Acknowledgement Form are in place, even if they know there is a 70-week wait for a neurology appointment – this is particularly problematic if the patient moves to England from overseas as some countries do not have access to anti-epileptic medications which are safer in pregnancy
- a lack of interoperability, so community pharmacists are not able to access prescribing information from secondary care or GP systems
- a lack of confidentiality if pharmacists ask patients about contraception in the community pharmacy, particularly in smaller communities, which acts as a barrier to safe use of valproate

95. Despite the multitude of issues, the Commissioner has also seen pockets of excellent clinical practice with regards to valproate within integrated care systems which can review the entire patient pathway, from hospitals through to community contraception services, GPs and community pharmacies.

96. The challenge is ensuring clear and accurate information at a national level which is then consistently applied at a local level across the country – and that this work is monitored and evaluated. In this space, like many others, there is often a difference between plans to improve and on the ground actions. A postcode lottery for patients is not acceptable.

97. While causing avoidable harm to patients, these gaps and inconsistencies are also potentially costing the government large sums of money. According to the recent research from the Office of Health Economics (commissioned by the Epilepsy Society), the total cost per case of harm from exposure to an anti-seizure medication such as valproate during pregnancy ranges from £2.5 million in severe cases of Autism Spectrum Disorder, £927,000 for spina bifida and £124,000 for a child born with Attention Deficit Hyperactivity Disorder.[79] These costs are incurred by the family (and we discuss in chapter 3), the NHS, the education system, the welfare system and wider society. Therefore, in addition to all the other compelling reasons, there is a clear financial imperative to get this work right.

98. Valproate also is only one example of a potential teratogen – a substance that causes or raises the risk of a birth defect in a developing foetus. For many of these substances, patients have a far lower awareness of their risks compared to valproate.[80] There is a pressing need to better monitor the safe use of these medicines more generally.

99. As a result, the Commissioner issued the following recommendation to NHS England in November 2023, designed to improve patient safety for patients:

> **"The Patient Safety Commissioner recommends for NHS England to have a fully funded and resourced system for improving the safe use of the most potent teratogenic medications, through a National Quality Improvement Programme for Integrated Care Systems, starting with the safe use of valproate. The Commissioner believes that this should be implemented by September 2024 for valproate, before expanding to cover any medication with a Pregnancy Prevention Programme by September 2025."**[81]

100. The Commissioner hopes that this recommendation will bring sustained focus on these issues and improvements in patient safety. As of December 2023, we are awaiting NHS England's response.

Specific developments with regards pelvic mesh

Increased data collection

101. Recommendation 7 of the First Do No Harm review called for the creation of a central patient-identifiable database with key details of the implantation of all devices at the time of the operation and linked to specifically created registers to research and audit the outcomes of the device safety and patient reported outcome measures. The First Do No Harm review team's appraisal of progress (referenced above) marked the implementation of this recommendation as in progress.

102. Since summer 2022, NHS England has started developing a new Medical Device Outcome Registry (MDOR). Unlike the wording of Recommendation 7 ("all devices"), MDOR is focused on those who receive high-risk medical devices, such as implants.[82] A phased roll-out of MDOR is planned in selected hospitals and is due to be complete by spring 2024.[83] By this date, all trusts should have adopted unique device identifier barcodes to support registry data submission.

103. A pelvic floor registry is already operational in NHS England and an improved version, integrated with the MDOR, is in pilot and due to be released with the wider platform in May 2023.

104. The Commissioner has engaged with NHS England on this topic since her appointment. In particular, she has articulated the importance of having patient groups and patient representatives on the relevant programme boards – which she is pleased to see is starting to take place.

105. However, the limitation of MDOR to "high-risk" medical devices relies heavily on the accurate identification of such devices in advance of their widespread use. This is hard, particularly without longitudinal data. The key question everyone involved in this work must ask themselves is would mesh have been designated as high-risk if the MDOR existed in the early 2000s?

Audit on pelvic floor surgery and development of a new patient reported outcome measure

106. NHS Digital has undertaken a retrospective audit of all pelvic floor surgery completed between 2006 and 2011 to generate a historical baseline of outcomes by procedure type and to support further research and analysis. The audit captures subsequent procedures and re-operations over a 10-year period after the initial procedure using Hospital Episode Statistics data.[84]

107. In April 2023, the government stated in a response to the Health and Social Care Select Committee that the audit was undergoing peer review with a view to publish later in 2023. However, in October 2023, NHS England informed us that the study had encountered data challenges and, as a result, was not currently approved for publication. No further information on when publication was likely was provided to us.

108. Sadly, these delays only illustrate a fundamental problem with pelvic mesh, which is that the data collected on its use and outcomes has not been good enough to allow patients to give informed consent to these procedures.

109. To help fill this gap, the National Institute for Health and Care Research has commissioned the development of a validated patient reported outcome measure for pelvic floor disorders. The study, APPRAISE, started in May 2023 and is led by Leeds Beckett University. The study will develop a questionnaire which will help women report how pelvic floor surgery has affected their quality of life.

110. Development, testing, evaluation and validation of this new patient reported outcome measure is likely to take around three years and requires patient, clinical and specialist academic input to ensure that the data collected is suitable for outcome-based analysis and evaluation.

Specialist mesh centres

111. As stated above, Recommendation 5 of the First Do No Harm review recommended the creation of specialist mesh centres.[85]

112. NHS England published the service specification for specialised services for patients with complications of mesh inserted for urinary incontinence and vaginal prolapse in March 2021.[86] This led to the establishment of nine complex mesh centres across England.[87] To date, we understand that around 1,900 women have been referred to one of these centres for treatment.[88]

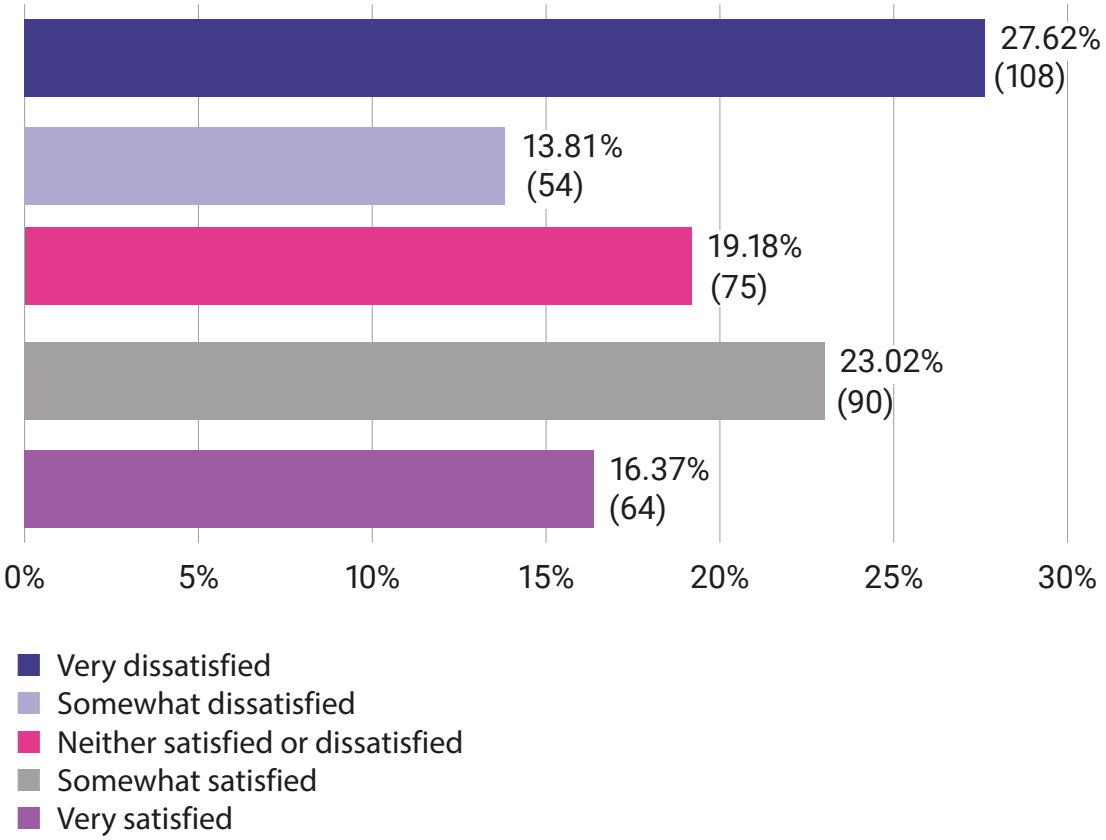
113. As a general principle, the Commissioner believes that patient voice should be included in the design and delivery of services. The Commissioner challenged NHS England to include relevant voices in the design and language of the mesh specialised services national specifications. The Commissioner was pleased that NHS England took this feedback on board and made the necessary changes.[89]

114. The stated aim of these centres is the management of continence and prolapse mesh complications, with the engagement of the multi-disciplinary team, including gynaecologists, surgeons, physicians, imaging specialists, nurses, pain specialists, physiotherapists and clinical psychologists.

115. A detailed examination of the performance of these centres and patients' experiences of them is beyond the scope of this report. However, we think that they are an important part of the non-financial redress for mesh harmed patients that we discuss in chapter 4. It is imperative that patients, after years of being dismissed by healthcare professionals, are not let down again by these services. As a result, we did ask one question in our survey about patients' experiences of these centres.

116. Our survey results present a mixed picture. There were almost equal numbers (32.4% versus 34.2%) expressing the view that they were either satisfied or dissatisfied with the specialist mesh centres. The survey responses from those who said that they had used the mesh centres (83% of all respondents) are shown in figure 2.

Figure 2: How satisfied are you with the NHS specialist mesh centres? ('N/A' respondents removed)



Source: Patient Safety Commissioner, Patient Engagement Survey[90]

117. Our patient engagement sessions also reflected this split of opinion. Many patients we engaged with did speak positively of the mesh centres and the care that they received there – for example:

> **"What a difference, what a beautiful difference in the way they treat you. You do feel that they are working as a team... and that the team is not just coming up with standardised treatment patterns and that they are thinking out of the box."**

> **"One of the things I don't feel is this hurry, this rush to get you out of the door."**

> **"It's lovely for me to be able to say could I go to the pain centre, and can I get this looked at, and he comes back and says yes that's a brilliant idea. That gives me empowerment."**

118. Other patients have had more negative experiences. Some felt that the wraparound care that should be provided as part of these centres was not in place:

> **"Often high-quality pelvic floor physiotherapy is needed after removal and women are just not getting it."**

119. Another patient raised concerns about the cost of travel to the centres and also felt she was discharged too early following removal:

> **"It's cost me an absolute fortune. And then when you come out of the operating theatre, they can't get you out of the wards quick enough. I had to get the train with 25 staples and all the rest of it, in a wheelchair and then I had a two-and-a-half-to-three-hour journey home."**

120. The Commissioner has previously expressed her concerns about wait times, the variation in provision of services and the distances that some patients must travel to access their services.[91]

121. She also pointed to the lack of information available to patients and GPs, who may not be aware of the complications of pelvic mesh or the option to refer to these specialist centres. As a result, the Commissioner co-produced a resource with affected patients and a wide range of healthcare professionals in May 2023 to help support discussions with GPs. This resource takes the form of a letter that patients can take to their GP explaining pelvic mesh and the known complications as well as the referral options, including setting out the possibility of a direct referral to a specialist mesh centre.[92]

Overall – pelvic mesh

122. Many positive steps have already been taken. In particular, the use of pelvic mesh has been paused,[93] and a national specification for mesh removal centres drawn up and rolled out by NHS England. We are also pleased that work is underway on the new patient reported outcome measure for mesh surgery – though full implementation is still a number of years away.

123. But specialist mesh centres – once setup – must also deliver for harmed patients and here the picture is more mixed. Providers must involve patients in the design and operation of these centres in a meaningful way, so that outcomes and experiences start to improve.

124. There are also recurring issues with a lack of reliable, long-term data relating to the use of pelvic mesh. We think that these issues need to be resolved before any reconsideration of the current pause.

Overview of the international redress context

125. The harm caused by pelvic mesh and valproate is not confined to England and different countries have started to confront the issues caused by it.

126. A number of other countries have started to realise, as this report does, that addressing the legacy of harm caused by pelvic mesh and valproate is best done through the creation of non-adversarial, government-backed schemes. For some, such as New Zealand, these build on existing legislation.

New Zealand

In April 1974, New Zealand created a no-fault compensation scheme for accidents and injuries. This scheme now includes specialist guidance for harm from valproate exposure and pelvic mesh.

The scheme is administered by the Accident Compensation Commission, a public body, with the funding for treatment injuries provided by central government.

In 2019, the New Zealand Ministry of Health led a process to hear directly from those harmed by surgical mesh. The restorative justice project heard from 600 people and its report made 19 recommendations, one of which was to establish a specialist service for those suffering from mesh complications.[94]

France

In 2002, as part of a package of reforms on patient rights, France created a framework for an out-of-court system for compensating healthcare injuries through a public body called ONIAM.

France then created the specific Valproate Scheme for in utero valproate exposure before 31 December 2015. It started operation on 1 June 2017 and is administered through ONIAM.

The Valproate Scheme is underpinned by liability but there is no need for the claimant to demonstrate any fault on the part of the healthcare provider and the scheme is funded by the state.[95]

Pelvic mesh claims and claims for in utero valproate exposure with a prescription date after 1 January 2016 are assessed using the general scheme for medical accidents and injuries.

Scotland

The Scottish Government set up two funds for patients harmed by pelvic mesh.

The Scottish Government Mesh Fund ran from 1 July 2020 to 30 June 2022. This was a £1 million fund to support women harmed by mesh complications. It was never advertised as a redress scheme. Successful applicants to the fund received a one off-payment of £1,000.

The Transvaginal Mesh Removal Reimbursement Scheme allows anyone resident in Scotland who paid for qualifying mesh removal surgery before 3 June 2022 to make a claim to have the cost of their surgery reimbursed, as well as any associated travel costs. If the person has died, their next of kin are eligible to apply. The scheme also covers the cost of an individual who supported the patient to attend surgery.

Where does this leave us and the question of redress?

127. Many of the developments described above in relation to England are positive. However, they fall far short of what could be described as a comprehensive, government-backed and restorative redress scheme designed to repair the harm experienced by patients. This inaction is compounded by the government's rejection of the creation of an independent Redress Agency. There has been no progress towards providing harmed patients with any form of financial redress despite their needs. This contrasts with efforts in other countries.

128. As set out in chapter 3, we believe that a non-adversarial, easy-to-access redress scheme covering financial and non-financial elements for those harmed by valproate and pelvic mesh is the best way forward. Many of the non-financial elements of the proposed redress scheme set out in chapter 3 would be able to build on the foundations provided by recent developments outlined in this chapter. In other areas, such as access to benefits and the financial elements of any redress scheme, more work will be required.

129. But this work is necessary and vital. Providing restorative redress means, firstly, breaking the cycle of avoidable harm caused by pelvic mesh and valproate to allow patients any chance of moving forward. We cannot be in a position where we are talking about redress for another medicine or medical device in 10 years' time , because lessons from the First Do No Harm review were not implemented effectively.

130. As the National Advisory Group on the Safety of Patients in England put it:

> **"The only conceivably worthy honour due to those harmed is to make changes that will save other people and other places from similar harm. It would add tragedy to tragedy if the nation failed to learn from what happened, and to put those lessons to work."**[96]

Chapter 3:

The patient experience

> "There's gaslighting and there's extreme gaslighting. I really did have mesh and lots of it… who is carrying the can here for this? No one really. Just me."
>
> (Pelvic mesh harmed patient)

> "You have a child affected. But the whole family are affected. You have mum who has already got a disability with epilepsy, bipolar, etc. then children are born with disabilities… That is very hard to take on as a family."
>
> (Parent of valproate harmed patient)

Summary

- Our principal purpose of this patient engagement was to understand what needs patients have, so that any redress scheme we recommend meets those needs.
- We start with an overview of the physical and psychological harm generated by valproate and pelvic mesh.
- We then look at the broader impacts of harm – including impact on family and friends, life plans, the financial impact and the impact of not being listened to by the healthcare system.
- We also examine difficulties in access to public services such as social security benefits and special education needs services.
- We conclude by detailing the responses we received from patients when we asked them what difference a redress scheme would mean for them.

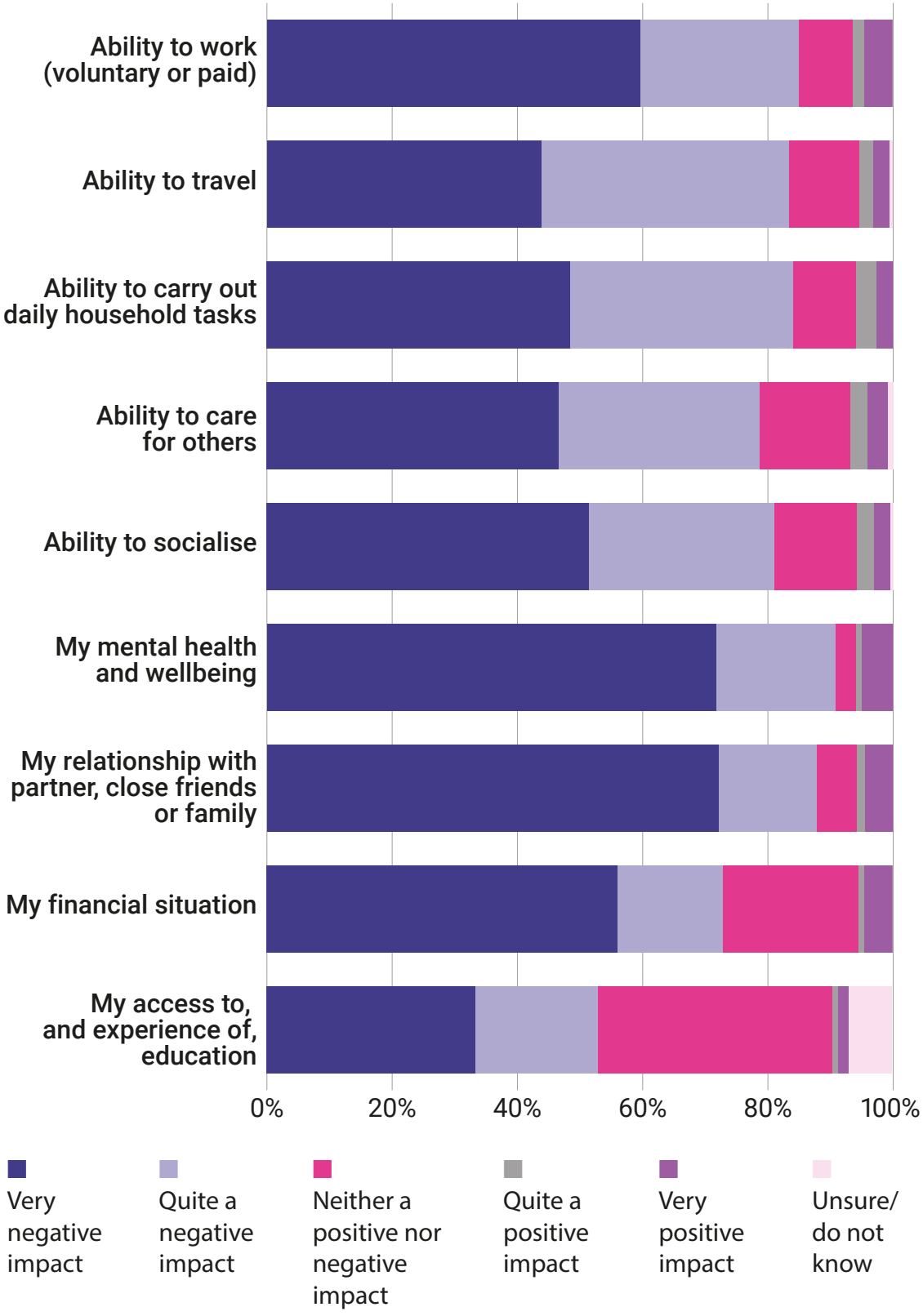
131. The patient experiences we heard during our engagement are harrowing and the themes that arose mirror those in the First Do No Harm review.[97]

132. Our understanding of patient experiences has also been aided by the APPRAISE team at Leeds Beckett University's early findings from their analysis (which included illustrative quotes) of seven patients who had mesh for POP and/or SUI.[98] These patients were interviewed as part of a larger UK qualitative study that explored the experiences of living with, and being treated for, urogynaecological conditions (PURSUE study).[99] The APPRAISE team have been conducting a secondary data analysis on a subset of interview transcripts to inform the development of a new surgery-specific patient reported outcome measure for women who have POP, SUI or mesh complications.

133. We concluded chapter 1 by stating that the developments to date had fallen far short of constituting a comprehensive redress scheme. This chapter illustrates the very real consequences of this failure. Figure 3 provides an overview of the breadth of the impact of the harm that patients and their families have suffered as a result of pelvic mesh and valproate. These results support previous studies, where it was commented "how wide-reaching and life-changing vaginal mesh complications can be".[100]

Overall impact – our survey results

Figure 3: How has valproate or pelvic mesh impacted the following aspects of your life?



Source: Patient Safety Commissioner, Patient Engagement Survey[101]

Case study 1

"I am unable to work and have given up my career due to my mesh injuries. I suffered for years with pain and infection and was constantly fobbed off when it was all down to the mesh. I have Post-Traumatic Stress Disorder and have been diagnosed with Lupus since the mesh was fitted. I rarely leave the house as I am now totally incontinent after having the mesh removed last year. I had to have a further operation to try and correct this which has resulted in permanent nerve damage. I am unable to be intimate with my husband or do any of the exercises I used to love. I have little energy to be a proper mum to my children who basically look after me since I gave up work. I did not consent to having mesh fitted in the first place and was NOT incontinent before I had it fitted during a gynaecology operation in 2016. My entire life has been changed forever due to the mesh and the damage it did to my insides."

(Mesh injured patient and respondent to our patient survey)

Physical and psychological harm

Pelvic mesh

134. Patients with pelvic mesh provided descriptions of intense physical pain associated with mesh complications: "I felt so unwell I can't explain the pain to you, I used to sit in my kitchen crying." Patients described how their mesh was "stuck to my pubic bone, it is stuck to my bladder, somewhere all over the place" and how strong pain killers failed to dim the pain:

> **"Nothing is ever going to take this [pain] away. I can knock back co-codamol, I can stick lidocaine plasters on and it might make me sleepy or groggy but the pain breaks through that medication."**

135. In their secondary data analysis, a subset of mesh patients, who were interviewed as part of the PURSUE study, described experiencing excruciating pelvic pain, feeling as though "somebody is drilling through the top of my groin areas". Patients described pelvic mesh as being "like barbed wire" and how they experienced "constant discomfort in the lower abdomen" which affected their day-to-day activities, particularly those that take place seated such as driving.

136. This same subset of PURSUE patients often described pain being worse at night, with a consequent negative impact on sleep. A patient told us that she would "wander around the house at night actually opening cupboard doors to see if I can find something to eat to try to get my mind off the pain". Reduced mobility because of the mesh and the impact of the pain meant that multiple patients reported sleeping on a separate bed downstairs.

137. Across many patients, a key theme was experiences of tremendous fatigue – with many describing having to go straight to bed at the end of the working day. One patient said to us: "I've always been a very active person. Some days now I do one or two things and I have to lie down. It is ridiculous."

138. Patients also voiced their anxiety about confronting a future filled with this level of pain alongside managing getting older:

> **"It is actually quite daunting to think, well I'd like to be here another 20 years… I'd like to see my granddaughters get married. But 20 years of this pain, I'm going to be pretty shot. I don't think many women are going to get through another 20 years of this."**

139. Alongside the physical pain, we heard about the psychological harm patients with mesh had experienced, with many reliant on counselling: "[The charity] Mind have continued seeing me, and without them I don't think I would be able to tell you all this." Some of the younger women we met had also, tragically, lost their choice to try for another child.

140. Patients who spoke with us flagged that they were coping better than some, while acknowledging that they understood how other women felt: "I completely understand the number of women that are crying and want to die." Tragically, women running patient support groups reported that some patients had made the choice to end their life.

Valproate

141. The complex and lifelong nature of the harm associated with valproate exposure means that those exposed face significant challenges with their ability to live their daily lives independently. Children and young adults often require additional support in education – and as children become adults, many continue to need support to care for themselves. Their ability to carry out household tasks, get employment, advocate for themselves, navigate social and romantic relationships, use public transport, and manage money can all be negatively impacted by valproate exposure.

142. Parents of children harmed by valproate described, in detail, the range of ways valproate exposure had impacted their children's neurodevelopment, including learning disabilities, cognitive processing difficulties, Autism Spectrum Disorder, Attention Deficit Hyperactivity Disorder, difficulties understanding circumstances and consequences of actions, reduced short term memory, and speech and language difficulties, including language sequencing issues:

> **"His short-term memory is down to the first percentile; the minute you've said something he turns away and he's forgotten what you've said to him… There is no way he would be able to live a life by himself."**

143. The result is lifelong care needs:

> **"They are all autistic. That's got to be borne in mind with this. These children, they're not going to get better. If anything, they're going to get worse."**

144. Parents also described the physical problems their children experienced, including suffering from scoliosis (abnormal curvature of the spine), abnormalities in the development of their feet and ears, and severely reduced mobility – including for some to the point of being bed bound.

145. Some families also described how their child's mental health had been affected by these conditions, emphasising that those exposed to valproate often suffered from depression and anxiety, including social anxiety. Recent research, helpfully shared with the Commissioner pre-publication and led by Sonia Khanom of the University of Manchester, has highlighted that the lifelong consequences of valproate exposure correlate with a notable decline in mental wellbeing as young people age.[102]

146. Families emphasised that the mother of the harmed child suffers from either epilepsy or bipolar disorder and will have to manage the challenges of that disability alongside their child's valproate associated disability. This has accurately been described as a "a double disability". As a valproate advocate told us: "It is hard enough to live your life suffering with epilepsy… But if you add to epilepsy having to look after a child with this condition… you really are doubly injured."

147. This harm has caused parents understandable worry about their children's futures and who will care for their children when they pass away. We heard accounts from mothers concerned about the deterioration of their health due to epilepsy and how this would impact their child. They describe themselves as "not in a fit state of health" with concerns that "many of us will become completely incapacitated in our roles as carers in the next 10 years".

148. We were also pleased to see that our findings aligned strongly with the recent research cited above. In that study, six broad themes were identified in terms of the lived experience of young adults harmed by valproate – namely health and development, employment, daily living and independence, social skills and relationships, access to services, and impact on families.[103] The research also sought to gather views on what support is required for individuals to meet these needs, which we come back to in chapter 4.

Impact of harm on relationship with family

149. The harm caused by both valproate and pelvic mesh has impacted patients' relationships with family and friends. For those suffering from pelvic mesh complications, many reported to us their ongoing intimacy issues.

150. The subset of patients on the PURSUE study described it as "heart breaking" to see their relationship change, as their partner had to take on more caring responsibilities:

> **"He's really tired most of the time. He's coming home, he works full-time, comes home from work and he cooks the food and takes the dog out, washes the dishes."**

151. This has led patients to have feelings of guilt and low mood: "I feel very guilty, you know, for my husband. I feel for him." Patients also reported that the effect of mesh complications on their personal relationships was broader than just their spouse and impacted relationships with their children and other family members, with children often becoming carers to their mothers:

> **"In my case, my youngest daughter was 12... they'd seen a really busy, proactive woman... I was screaming in bed and my 12-year-old had to get me for three years to the toilet."**

152. Families harmed by valproate echoed these points: “Families have completely broken down because of the stress of dealing with children who need help.” This meant that some mothers ended up as single parent carers for children and young adults with complex needs, while dealing with their own disability.

Impact on life plans

153. During our conversations we heard about how both valproate and pelvic mesh had impacted patients’ life plans and hopes for the future.

154. For pelvic mesh patients, we heard accounts from women whose retirement plans had been ruined: “What it is has cost me is my retirement. It has really taken a lot of the best years of my life away.” Patients who had looked forward to travelling during their retirement said they now felt too scared to go away for fear of developing or having to deal with a urinary tract infection while on a plane. Patients also reflected on how their suffering had caused them to miss out on time spent with loved ones: “I lost a lot of time with my family and I’m never going to get that back.”

155. For families harmed by valproate, parents’ natural hopes and ambitions for their children were replaced with worry and fear for the future. The additional support required for those harmed meant that family life and was increasingly shaped around their care. Parents described how their children’s lives differed from those of their peers: “All of their friends are out now getting jobs or getting married and they [their children] are so behind in their educational journey.”

156. We also heard from parents who had a sense of having missed out on building the life they desired for themselves and their family:

> **“I feel very upset that after all of the studying and the work I’ve done to try and pay for myself and make a future for myself and my family that I am unable to do that because of my son’s needs.”**

157. While mothers described loving their children and being a parent, they found that providing round-the-clock care left them with little time for themselves. As one patient put it: “I have had my life removed from me.” This impacted on the mental and physical health of carers: “I need to be able to go out or my mental health is going to deteriorate and I’m not going to be able to look after my son.”

Financial impact

158. The financial impact of harm was significant. Patients suffering from pelvic mesh complications have lost their jobs due to having to take time off for medical appointments and due to illness. Parents of children exposed to valproate have had to give up work to take on caring responsibilities:

> **"The wage stops, and you have the carer's allowance and maybe income support coming in, but that's just not enough to keep the family going when you've got three disabled children, or however many children you've got."**

159. We heard accounts of women having to abandon their much-loved careers and businesses that they had worked hard to build over many years. One patient explained that: "I used to run a very successful [business]… I earned a fortune, that was my key income, but I've had to close that." Another described how: "I had my [business] for 30 years, and to go for a minor procedure and come out in a wheelchair is totally unexpected."

160. Patients and families lost their homes due to the loss of income. For all patients, the loss of employment has caused significant fears about the loss of pension entitlement.

161. Parents with children exposed to valproate expressed a strong desire to own their own home to provide stability for the future of their children, although their financial circumstances did not enable this: "The majority of families are begging for enough to put down a deposit for their own home."

162. Patients talked about the cost of care as an additional financial burden, with some pelvic mesh patients spending thousands of pounds on train fares over the years to attend medical appointments often at specialist centres miles away from their homes: "Seven years later, I've spent £5,503.40 on train fares." Many were also paying out of their own pocket for private medical care and therapies.

Patients confronting a culture of disbelief

163. The First Do Harm review outlined how harm was compounded by the fact that patients did not feel listened to when they sought help from medical professionals.

164. Multiple patients with pelvic mesh used the term 'gaslighting' when describing the way medical professionals treated them when they were looking for a diagnosis. One patient explained how a consultant was "sitting there rolling his eyes" when she went to him for a second opinion and how he stated: "What's the point in [you] having a diagnosis if we can't do anything anyway?" Another explained how her surgeon responded in a letter when she raised the issue of uninformed consent and requested her medical records:

> **"I got this letter [from the surgeon]… and it's blaming me for everything, it's an absolutely shocking thing and it nearly gave me a nervous breakdown… I am not a liar but if you read this letter, it looks like I am just some moany woman who is fortunate enough to have seen one of the most eminent gynaecologists in the UK… That letter was a total betrayal."**

165. Female patients also felt their gender and age impacted the way medical professionals treated them:

> **"I think there's part of this medical misogyny – I am a woman of a certain age, I'm slightly overweight, I'm a mum, not working, so I'm not given credibility."**

Epistemic injustice

The experience of pelvic mesh and valproate harmed patients set out in this report and in the First Do No Harm review is not uncommon. Far too often when people voice inconvenient truths, the healthcare system turns its back and fails to listen and act.

What is behind this culture of disbelief that we see again and again, despite all those involved in healthcare generally pursuing their careers with the aim of improving the lives of patients?

The Commissioner believes that, at the core of this issue, lies a concept known as epistemic injustice. This concept provides a useful framework to understand both the issues in this report, as well patient safety culture more widely. 'Epistemic' means relating to knowledge and 'epistemic injustice' occurs when a person has their knowledge denied, undervalued or undermined. It has also been described as a "double-standard in evidence-based practice".[104]

Epistemic injustice is fundamentally about power structures in which some people are more readily believed, some forms of knowledge are more highly valued, and some people have a greater ability to explain their knowledge in a way that those in power are receptive to.

Epistemic injustice frequently intersects with equality characteristics such as age, race, sex and disability, with members of certain groups more likely to be disbelieved and disempowered.

Epistemic injustice is not a concept unique to healthcare, but within it finds fertile ground. Healthcare and medicine are specialised disciplines run by highly qualified individuals. Consciously, or unconsciously, these individuals often prize certain types of knowledge over listening to and hearing (particular groups of) patients. This attitude often results in patients being undermined in their capacity as knowers of their own bodies – for example in relation to what symptoms or side-effects they are experiencing or what treatment is best for them.

Unless the health system recognises, understands and addresses this epistemic injustice, avoidable harm will continue, and the Commissioner welcomes the CQC's recent work on a human rights approach in this space as an important first step as part of this.[105]

Access to social security benefits

166. During our engagement we heard accounts that public services available to patients were inaccessible, time consuming and very difficult to apply for. In some cases, services were not well advertised or communicated to the population harmed.

167. Challenges with the Personal Independence Payment (PIP) system were raised by both groups of patients. Patients with pelvic mesh described applying for PIP as similar to "jumping through a hoop", "degrading" and having to "bend over backwards" to prove their condition existed. Patients stated that the money from PIP would be useful to pay for wraparound care such as physio and counselling, but they described not having any energy left to apply for PIP at the end of the working day:

> **"I don't have anything left to be able to fight for some money for the stuff I need, my key ones are probably physio. I have regular physio that I pay for myself. I probably need counselling, but I haven't got enough money after all my bills are paid."**

168. Parents of children exposed to valproate described a "constant battle" with applying for PIP as often families might have it "for two maybe three years and then they are bringing you back in for assessment". Families wanted greater certainty of PIP.

Access to education services

169. With children exposed to valproate, there were further challenges of access to specialist education services. Parents described 'fighting' with local authorities so their child could attend a supported college rather than a mainstream one:

> **"He did get the supported college but only because we fought for it. The local education authority didn't nominate this school, they didn't tell me about this school, it's only because I found it myself… You've got to search for it yourself and that's wrong."**

170. Concerns were raised about the Education, Health and Care Plans available to children and young adults who need additional support. Parents described the process of getting a care plan as very long with frequent re-assessments: "It took 4 years initially to get a statement put in place for one of them, and then every year you'd have to go to the reviews and fight to keep it in place." Other parents complained about not being able to secure an Education, Health and Care Plans, despite being in possession of a diagnosis of FVSD for their children – a diagnosis which, in itself, is a challenge to obtain, as we discuss below.[106]

171. Further concerns were raised over the fact that the plan only went up to the age of 25, when the child's educational journey would take much longer than a child without neurodevelopmental issues.

Access to mental health services

172. Poor access to mental health support also came up during the patient engagement discussions: "The older they get, depression and anxiety sets in, it just spirals for them. There's no support for them." Parents reported long waiting lists to access care even when their child was actively self-harming. Services offered were often inappropriate to meet the needs of the child such as days out. Patients suffering from pelvic mesh complications also expressed a need for sufficient mental health support.

Experience of legal routes

173. Patients' experiences of seeking redress through legal means have highlighted the clear benefits of a non-adversarial, government-supported redress scheme that we advocate for in chapter 3. Too many patients conveyed their experiences of being let down by the legal system – even when they think they have a strong case. The nature of the adversarial legal system means that factors and issues that claimants feel are irrelevant become relevant, leading to a lottery in terms of success.[107] For those who have been successful in their claims, litigation cannot award the type of holistic, restorative support that patients require to move forward with their lives.

174. Patients have faced huge challenges going through legal routes, either clinical negligence claims or product liability cases. For example, cases have been dropped by legal representatives without warning and patients have had to find new solicitors under impossible timeframes. We also heard about patients' hurt and disappointment at having their case handled by a solicitor who was subsequently subject to a Solicitor Regulation Authority intervention in 2023.[108] Generally, time limits for bringing a claim were a common complaint. Patients also expressed the view that legal routes were stressful, time consuming and lacking empathy:

> **"Women have dropped cases because they can't deal with it. We've had women that haven't even had the strength to even consider taking a medical negligence case because they just can't put themselves through it."**

175. Families with children harmed by valproate talked about their frustration of participating in a large group class action against Sanofi that spanned from 2005 to 2010, where legal aid funding was withdrawn just before the case was meant to go to trial.

Conclusion: what difference could a redress scheme make?

176. Redress for those who have been harmed cannot change the past. But it can demonstrate that the government has listened and responded to the needs of those harmed.

What would a redress scheme mean to patients?

Source: Patient Safety Commissioner, Patient Engagement Survey, thematic analysis of question 26

Case study 2

"Redress is essential for me to have access to life and support especially when my parents are not here anymore as I don't have siblings (obvious reasons – they did not want another child to be affected even though health professionals were denying anything was wrong, they knew something was) and may not be able to have my own children (waiting for research on whether FVSD is inherited). I am nearly 18 and urgently want to know if I can have children or not if they would be affected. I want others to have access to information and support rather than misdiagnosis or no diagnosis and no support in school or from health providers. I do not have an Education, Health and Care Plan and schools and colleges do not recognise your difficulties enough if you don't – colleges are worse and then adult life even harder. I will need more support than most people specifically because of FVSD. I need to have people around me, helping and I need entertaining. This doesn't come for free."

(Valproate harmed patient and respondent to our patient survey)

Financial support

177. As set out earlier on in this chapter, patients and their families reported significant loss of earnings due to the impact of their harm, which also affected their ability to contribute to a pension. Financial redress would help compensate for this loss of income. For families harmed by valproate, financial support would give parents some assurance that their children would have financial support when they pass on:

> **"The implementation of a redress scheme is vital to so many families with children who have FVSD. We don't know who will be around to look after our children when we are no longer able. Due to their disabilities caused in whole by this drug, chances are they will not be able to earn anywhere near the amount a neurotypical person can… This [redress] would help by providing some financial security for my son and I could relax a bit more knowing that he will have a roof over his head when I am gone."**

178. Financial redress would also help support patients with the considerable additional living costs they face, including home adaptions, higher energy bills, private medical care and therapies, costs for travelling to health appointments, and products to manage health conditions that are a result of the harm, such as incontinence pads. One patient summarised these costs as follows:

> **"I had to leave my [career] of 16 years on ill health retirement as I could no longer work. Getting benefits was hard and degrading, it affected my self-esteem and I was depressed and had counselling. My pension was reduced and very poor as I had to drop my hours from 28 per week to 15 and go down a band to remain employed which affected my final pension… I had to pay for train travel… and accommodation and also my husband who was self-employed had to take unpaid time off to accompany me for appointments and operations. We spent at least £5,000 on this and couldn't claim it back… My bills are higher than normal with my double incontinence and paying for incontinence pads is costly too."**

Non-financial support

179. The redress scheme that we propose in chapter 4 would offer non-financial support to patients to improve their access to public services such as social security benefits:

> **"Financial redress has never been a priority for me. Finding a solution to 10 years of chronic pain and mobility issues was always a main priority… The impact of quality-of-life issues with regards to employment, family life, social life and marital life has been severely impacted physiologically and psychologically."**

180. Action on a redress scheme will also provide substantive acknowledgement and recognition needed by many patients to move forward with their lives. While the government apology issued after the publication of the First Do No Harm was important, for many others it represented the symbolic – rather than the substantive – recognition they desire. As one survey respondent said:

> **"[A redress scheme] would help me immensely – to have written acknowledgment that I have been harmed by the implantation of pelvic mesh. This would enable my nearest and dearest to understand and accept why I am not the person I was prior to the surgery... It would give me confirmation that my fight for justice has not been in vain – [that] I have been listened to and understood."**

181. It is now for the government to listen to these voices of patients and take action. Chapters 4 and 5 describe what we recommend this action should look like.

Chapter 4:

Key features of a redress scheme for pelvic mesh and valproate

> "We would like to be in a position where we don't have to worry about our kids, we know they're going to be cared for, not just while we're around but the whole of their lives."
>
> (Parent of valproate harmed patient)

> "We're not going to get millions of pounds and nobody expects that, but I think we need acknowledgement… someone's got to acknowledge it and take responsibility… this is what is annoying and it's very upsetting for all these women."
>
> (Pelvic mesh harmed patient)

182. This chapter presents the options for the form and level of redress that would be appropriate for those harmed as a result of valproate and pelvic mesh. The lack of an umbrella Redress Agency with a governing set of principles – as recommended by the First Do No Harm review – means there is not a single way to 'do' redress in this country.

183. As a result, on each occasion that a scheme is required, there is nothing 'off the shelf' for the government to use. However, the government has numerous approaches that it could adopt or draw from, as this chapter illustrates, that reduces the need to come up with an entirely new scheme.

Key principles

184. Any proposals for redress, and their implementation, must be underpinned by clear governing principles. Sir Robert Francis KC produced a report in 2022 on compensation for infected blood, which included his recommended list of such principles.[109] There are clear parallels between patients harmed by valproate, pelvic mesh and the ongoing infected blood inquiry. In all these cases, medicinal products provided by the healthcare system have led to avoidable harm.

185. We do not believe there is any need for this work to be re-done and we endorse Sir Robert's principles, which are set out below.

Principle	Explanation
Remedial	The aim of a compensation scheme is, so far as can be achieved by provision of money, support and services, to provide eligible persons who have suffered injury or loss directly or indirectly from infected blood or blood, with proportionate redress for, and recognition of, the adverse experience they have suffered.
Respect for dignity	The scheme must restore and preserve applicants' dignity and treat them with respect and confidentiality.
Collaborative	The scheme should be collaborative with, and supportive of, applicants and, so far as possible, avoid an adversarial approach to claims: applicants should be believed unless the contrary is proved.
Choice	The scheme should respect and enhance the autonomy of applicants, including offering a choice of how remedies are delivered.
Individualised	Awards should reflect, in a proportionate and consistent manner, the individual circumstances and experience of applicants.
Inclusive	The scheme should recognise the direct impact of the infection and its consequences on the infected person, but also the indirect impact of the infection on those close to the infected person.

Principle	Explanation
Non-technical	There should be no bar to eligibility based on technical issues, such as limitation through the passage of time since the onset of the infection and its consequences.
Accessible	The scheme must be as readily accessible, understandable and free of complexity and stress to all potentially eligible persons, as is reasonably possible with appropriate assistance.
Ease of proof	Unjust, distressing and disproportionate requirements of proof and evidence should be avoided.
Broad	Measures of compensation should be designed, so far as possible, so that they are easy to apply and represent broadly fair, proportionate compensation for the injury and loss suffered as a result of the infection, with due consideration of, but without being bound by, the boundaries of entitlement to damages in law.
Improving	No claimant for compensation should be worse off than they would be without such a scheme, and an award of compensation should not prevent the pursuit of any entitlement to bring legal proceedings for the same subject matter.
Complementary	The continuing payments under the existing support schemes should be continued and made more secure regardless of any claim for, or award of, compensation.
Holistic	Compensation is not just about money but should also include consideration of material means to compensate for what has been lost.

186. We want to emphasise the importance of the 'respect for dignity' principle – which overlaps with respect for patients' psychological justice referenced in chapter 1. Too often, those affected by pelvic mesh and valproate have not been treated with dignity. Their voices have not been heard and they have not been told the truth or enabled to make informed choices. Any scheme must provide equitable redress delivered in a transparent and compassionate manner.

Non-financial redress

Summary

- Non-financial redress includes those programmes designed to support patients that do not involve the transfer of money to individual patients. Industry may be more willing to work with government on these issues.
- We have suggested a variety of areas where the government should consider non-financial redress to be part of a redress scheme, including:
  - access to public services
  - support and recognition for patient support groups
  - housing
  - healthcare
  - social security benefits
  - employment support
  - individual apologies
  - answering unaddressed questions
  - research and education

187. Over 90% (90.1%) of our survey respondents agreed or strongly agreed with the statement that 'effective redress for me is more than just a financial award'. This did not surprise us – promoting healing and bringing about positive change for people is more nuanced than simply awarding patients sums of money.[110]

188. By 'non-financial', we do not mean that these are necessarily of no cost to the government or the industry – although in many cases, we envisage the redress being improved access to existing services, rather the commissioning of new ones. Rather, they do not involve the transfer of money to individual patients. We do not envisage access to non-financial redress being governed by any additional eligibility criteria (other than the existing criteria in place for services such as social security and educational support).

189. It is only through a comprehensive redress scheme encompassing both non-financial and financial redress that we think that patients' substantive justice needs – as defined in chapter 1 – will be met.

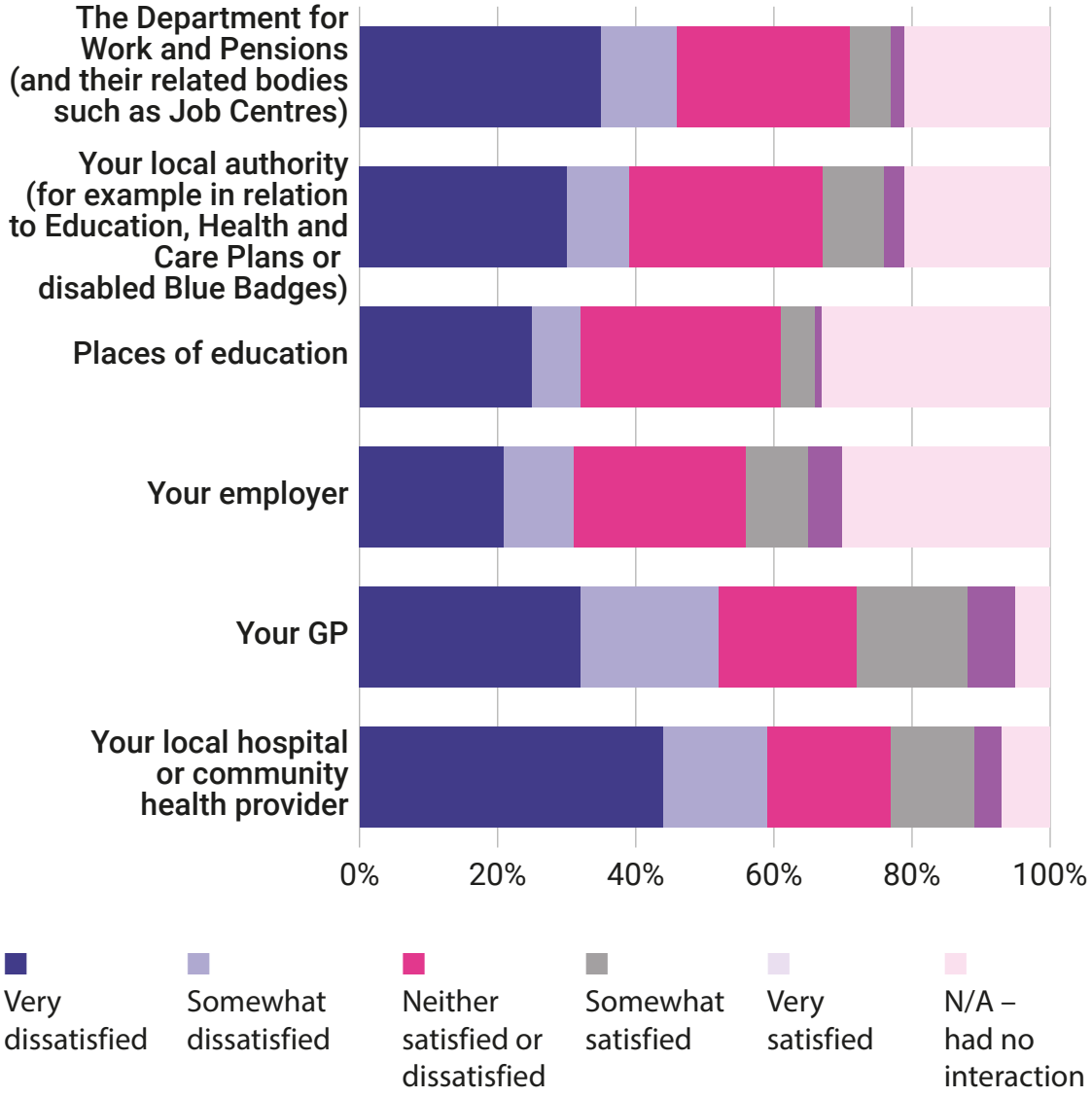
Recommendation 2

Redress should provide all those harmed by pelvic mesh or valproate with access to non-financial redress. To deliver this, the government should work with other government departments, the healthcare system and local authorities to measurably improve harmed patients access to, and experience of, public services.

Experiences of public services

190. Our patient survey revealed high levels of dissatisfaction of interaction with public bodies responsible for providing services and support.

Figure 4: Thinking about the times when you have interacted with different public bodies to access support and services for yourself or on behalf of others harmed.
How satisfied were you with their knowledge and awareness of valproate or pelvic mesh and the harm that these interventions have caused?



Source: Patient Safety Commissioner, Patient Engagement Survey[111]

191. To improve overall experiences, we suggest that the government implements something akin to a comprehensive social prescribing model for harmed patients and their families. For example, in Ireland, all individuals who have been infected with Hepatitis C from contaminated blood products are allocated a named Hepatitis C liaison officer.[112]

192. In the English context, a link worker could be provided to signpost patients towards available support and offer an advocacy service.[113] This will help eliminate the struggle of patients and families fighting to access services and generally make it feel like they have someone on their side.

193. 'Available support' in this context would include social security benefits, local authority services, educational support, housing, healthcare and employment. The link worker could be based within a redress scheme, a patient-facing part of the integrated care system or a local authority.

Support and recognition for patient groups

194. We had the privilege of meeting with some extraordinary patients who run campaigns and patient support groups over the course of this project. They have spent countless hours setting up and running these groups – while experiencing harm themselves –and often with very limited resources.

195. They have become vital hubs of support and community for harmed patients and because they are patient-led, have the respect of those that they represent. In chapter 5, we highlight the role that they should play in raising awareness of redress schemes with patients. But in addition, they need to be supported to continue doing the work that they are doing. One area that we think DHSC should explore is providing such support via the Health and Wellbeing Fund, which provides grants to voluntary, community and social enterprises.[114]

Housing

196. Housing is a key concern for patients. Patients need access to secure, accessible and affordable housing with the range of adaptations that their disability requires and the option of supported living where this best meets the patient's needs. As research noted, housing is key to promoting and supporting the need for independence that many of those harmed seek and deserve.[115]

197. To meet this need, the government should consider the launch of a dedicated housing support fund for those patients harmed by valproate and pelvic mesh. Patients and their families could then apply for support with home adaptations through this fund with the types of support available tailored to their housing tenure. This support would run alongside the financial support we recommend in chapters 4 and 5 which families could also use to support their housing needs.

Access to multidisciplinary and multi-agency healthcare support

198. We envisage that a key part of non-financial redress is the creation of multidisciplinary diagnostic and treatment support for those exposed to valproate and pelvic mesh, in line with Recommendation 5 of the First Do No Harm review and as discussed in chapter 2.[116]

199. As the specialist mesh centres are already operational, non-financial redress in respect to mesh under this heading requires continued close monitoring and evaluation of these centres and a culture of continuous improvement.

200. In addition, we've also heard from patients on the need for better and more regular proactive monitoring of their mesh in advance of any recognisable mesh complications – where there appears to be a gap. This could be co-ordinated by specialist mesh centres, in conjunction with GPs.

201. With regards to valproate, non-financial redress would involve building on the lessons learnt from the findings of the hub and spoke pilot, referenced in chapter 2, to create a national specialist service with sufficient funding and specialist workforce.

202. This work is so important because the research is clear that individuals harmed by valproate require substantial support from a wide array of services as they age, which means lifelong input from a variety of specialist health and other professionals.[117] It is also exactly what affected families have suggested themselves.[118] We know there is currently variation and inequitable access to such services.

203. But provision of this support through one or more valproate centres would also come with an additional benefit as it would increase the rate of FVSD diagnosis. Everyone that we spoke to agrees the condition is underdiagnosed within the harmed population. Addressing this issue is crucial because a formal diagnosis remains a gateway to many support services. A new centre will also be an important route for establishing eligibility for the financial elements of a redress scheme.

Social security benefits

204. Patients expressed dissatisfaction with access to social security benefits administered by the Department for Work and Pensions during both our engagement meetings, summarised in chapter 3, and in their responses to question 24 of our survey (shown above). Issues tended to centre on complaints about access to two types of benefit – PIP and carer's allowance.

205. PIP is designed to help with extra living costs for people with a long-term physical or mental health condition or disability who have difficulty doing certain everyday tasks or getting around because of their condition.[119] A person is eligible for carer's allowance if they care for someone who is in receipt of certain benefits – of which PIP is one – for at least 35 hours a week.[120]

206. The Department for Work and Pensions needs to provide patients with an improved service. Key suggestions for improvement are listed below.

- Improve assessment processes – including ensuring that Department for Work and Pensions decision makers use condition insight reports for pelvic mesh complications and valproate exposure consistently. We also suggest that ongoing work to train specialist assessors in various areas is expanded to create specialists in pelvic mesh and valproate harm.[121]
- Build better and more effective relationships between the specialist mesh and valproate centres and Department for Work and Pensions assessors. This also supports our suggestion of link workers, who could become the facilitator of these relationships.
- Review the intensity and frequency of PIP reviews for those harmed by valproate and those with pelvic mesh complications. We understand the Thalidomide Trust advocates for its beneficiaries for a 10-year 'soft-touch' review period with the Department for Work and Pensions. We understand that work is progressing on standardising the application and review process for those with the most severe disabilities through the Severe Disability Group, across a range of health conditions.[122] We have flagged to the Department for Work and Pensions the harm caused by valproate and pelvic mesh, and think the work of the Severe Disability Group would be beneficial to the extent that it becomes applicable.
- Provide clearer pensions information tailored to those patients harmed by pelvic mesh or valproate – including the option for face-to-face advice meetings. This information should include details about national insurance credits to make up for lost national insurance contributions, as awareness of these appears to be low amongst harmed patients. This service could be run through the Money and Pensions Service.

Employment support

207. While many of those harmed by valproate may be able to cope with education – where often support is in place alongside a regular structure – their disability makes finding and securing regular employment much harder.

208. Families that spoke with Sonia Khanom emphasised the need for specialised work experience programmes, providing practical training, counselling and job opportunities aligned with their children's strengths. This was alongside employers encouraging supportive measures like remote work, flexible hours and adaptable roles.[123] Suitable employment opportunities are important in providing independence, structure, a sense of purpose, social interaction and, of course, income.

209. As a result, we think that the link workers should be empowered to support those harmed with finding suitable employment and training opportunities. But to ensure that these workers have appropriate services to refer people to, the government should work with families to ensure that existing support services (such as Support to Work and Access to Work) are suitably tailored to those harmed by valproate.

Special educational needs

210. As discussed in chapter 3, parents complained of difficulties in getting local authorities and schools to recognise the needs of their children. This information gap needs to be filled.

211. To increase awareness of FVSD, we would support the creation of national guidance for local authorities on this issue and updating existing guidance with references to the condition and its effects. In addition, those in the Special Educational Needs and Disabilities Information Advice and Support Service need better training and support.

212. It is a fundamental principle of the special educational needs and disabilities system that provision is based on need, rather than a formal diagnosis.[124] This presents an opportunity given the current challenges in diagnosis of FVSD. However, more needs to be done to make this principle a reality. The specialist valproate centres referred to above are key in this regard – they should act as hubs of knowledge and support for parents, local decision-makers and national government. These centres could also work with our suggested link workers.

Individual apologies and acknowledgement

213. Almost 81% (80.9%) of respondents to our survey agreed or strongly agreed with the statement that 'receiving an individual apology (or apologies) is an important outcome of any redress process for me'. And yet, despite the government having issued an apology to patients and families in July 2020, only around 3% (3.2%) of respondents to our patient survey stated that the government has provided them with an adequate apology to date. Why?

214. A genuine and meaningful apology needs to incorporate the '4 Rs': regret, responsibility, redress and reform.[125] We covered our concerns with the status of the reforms designed to prevent mistakes reoccurring in chapter 2. Patients expressed to us concerns that the other three 'Rs' are also lacking.

215. Firstly, on regret, it was a generic apology. To tackle this issue, the government should consider how a redress scheme could provide more individualised apologies expressing regret to those applicants who wish to receive them. The list of bodies that patients said they would like an apology from in addition to the government was broad and included almost all the major organisations in the English healthcare system, including individual clinicians. While we understand that some clinicians may be nervous that any apology opens them up to legal liability, the government has options to mitigate these concerns.[126]

216. Secondly, on responsibility, some patients saw it as forced. One patient said: "Being told to apologise… is a lot different from realising you have made a mistake and standing up for what it right."

217. Thirdly, on redress, an apology is not seen as meaningful without action to meet the needs of patients, including the award of financial redress, and action to prevent it happening again.[127] As one patient said: "An apology is changed behaviour."

Answering unanswered questions

218. Almost 92% (91.8%) of our survey respondents agreed or strongly agreed with the statement that they still had unanswered questions about their harm and why it was allowed to happen. The desire for an answer to these questions is understandable, and research has shown that decisions to pursue legal claims are often motivated by a desire on the part of patients to receive an explanation.[128]

219. In our patient engagement meetings, we heard numerous calls for a review or public inquiry into what went wrong, particularly from those harmed by pelvic mesh. Patients felt that such a review was particularly important ahead of any decision to modify the pause on the use of pelvic mesh. It is important to relay the views of patients that gaps remain.

Research and education

220. There is still so much that we do not know about both interventions – particularly longitudinal research to allow for the identification of symptoms and challenges that may manifest over time.

221. For example, it is not known if, and why, certain women may have higher chances of experiencing complications following mesh implantation.

222. Across anti-seizure medications, there is a need for a greater understanding of how and why these drugs affect the developing foetus so we can gain a better understanding of how to more quickly and effectively diagnose the conditions associated with them.[129]

223. Dedicated research funds created by the government for pelvic mesh and valproate and other anti-seizure medications would help close these knowledge gaps and enable those harmed to participate in studies. These studies would also provide vital learning to help reduce the risk of these mistakes occurring again – a key element of restorative practice. It would represent a good return on investment, given the lifetime costs of supporting children harmed by anti-seizure medications, as discussed in chapter 2.

224. We are not alone in calling for this investment. The Epilepsy Society's Safe Mum, Safe Baby campaign is calling on the government to invest more in genomic research into safer epilepsy medications in pregnancy. This could mean better outcomes in the future for today's teenagers with epilepsy, when they look to start a family.[130] The forthcoming Epilepsy Research Institute also provides great opportunity to build on.[131]

225. Another area where we think that there is opportunity to improve is via the development of a digital Annual Risk Acknowledgement Form to enable monitoring of all anti-epileptic medications.[132] This innovation would address many of the issues that we identified in chapter 1. It would also allow follow-up and long-term outcomes of both male and female patients moved from valproate onto other anti-seizure medicines.

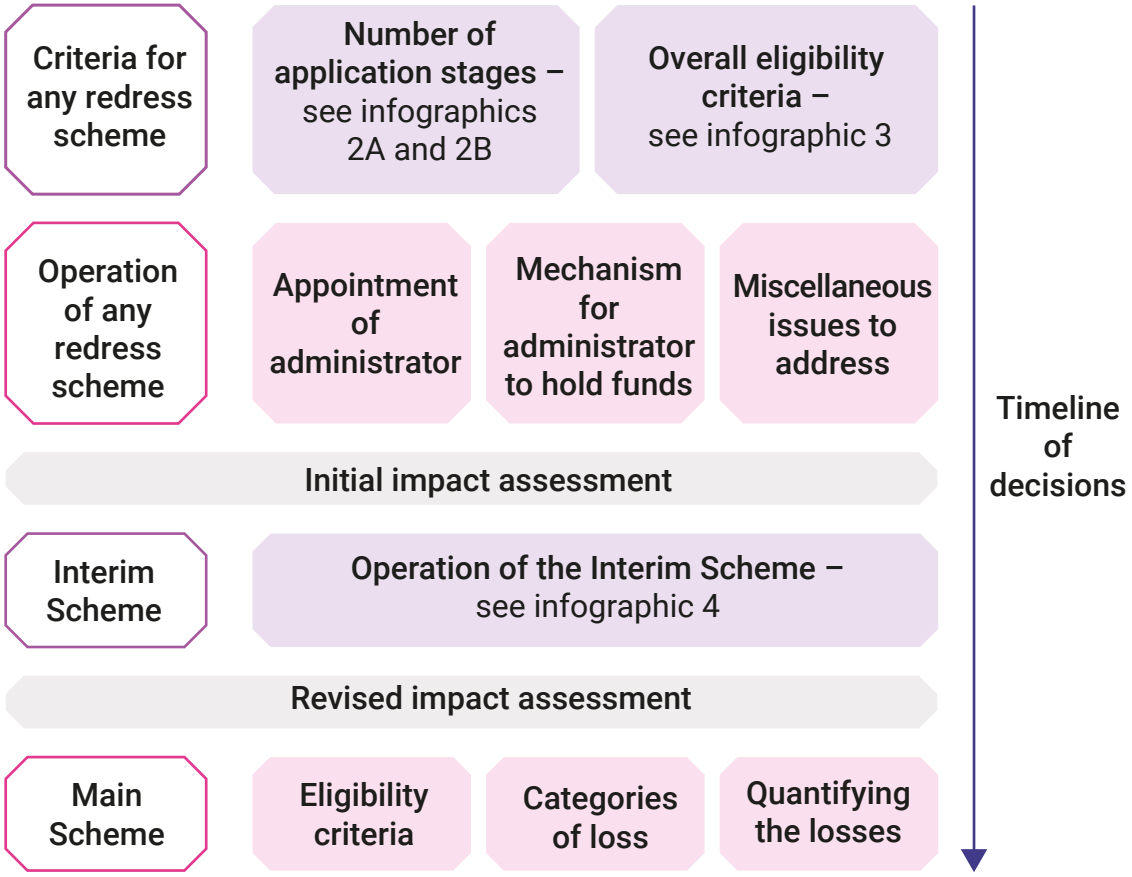
Financial redress

Summary

- We have presented two options for the overall format of any financial scheme:
  - a single stage scheme
  - a two-stage scheme formed of an Interim Scheme and Main Scheme
- We recommend proceeding with a two-stage scheme. This will provide quicker financial redress to patients and will give the government greater evidence on the size of the population harmed before they launch the Main Scheme. Responses to the patient engagement survey also supported this approach.
- Pelvic mesh and valproate caused harm to two distinct groups of individuals: those 'directly' harmed and those 'indirectly' harmed.
- Those directly harmed can be more be easily defined from the start. We suggest definitions applicable to those directly harmed by pelvic mesh and valproate, respectively, below. All those directly harmed should be eligible to apply for the Interim Scheme and Main Scheme.
- The definition of indirectly harmed is harder and requires further engagement with patients. We suggest the government considers excluding them from the Interim Scheme but including them within the Main Scheme.
- Provision needs to be made across both the Interim Scheme and Main Scheme for the estates of those harmed to apply – to cover those otherwise eligible but now deceased.
- NHS and private treatment should be covered by the Interim Scheme and Main Scheme.
- DHSC needs to discuss with the devolved administrations the question of a residency requirement and geographical place of treatment restriction.

226. Given our recommendation 3, the remainder of this report will focus on what it will take to create a two-stage scheme. Setting up the financial elements of two-stage redress scheme requires careful consideration of several different elements in the right order – as set out in infographic 1. Each of these elements will be examined in the text below.

Infographic 1: Headline issues relating to the financial aspects of a two-stage redress scheme that will be addressed in the sections below



227. This section is designed to provide patients, government and broader stakeholders with an overview of how to approach these different elements as a starting point. In many areas, there is further work that will need to be completed by the administrators of the scheme.

228. We also hope that this section provides a template that has a broader applicability to the thinking required before the creation of redress schemes more generally.

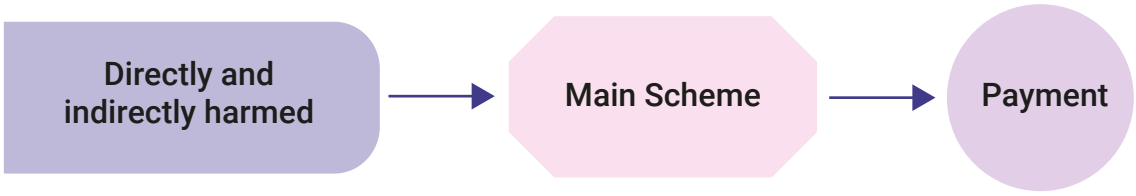
229. In some areas, we have set out recommendations from the various options discussed. This is particularly true when we discuss the Interim Scheme. In other areas – notably with respect to the Main Scheme – we have kept to a broader discussion.

Overall structure of a financial redress scheme

Proceeding immediately to a single-stage scheme for pelvic mesh and valproate

230. The first option would be to immediately create the Main Scheme for valproate and pelvic mesh, covering those directly and indirectly harmed. This would mean that there would only be one stage for patients to navigate – with the option to receive individualised payments from the date of the scheme's creation. This option is illustrated by the flowchart below.

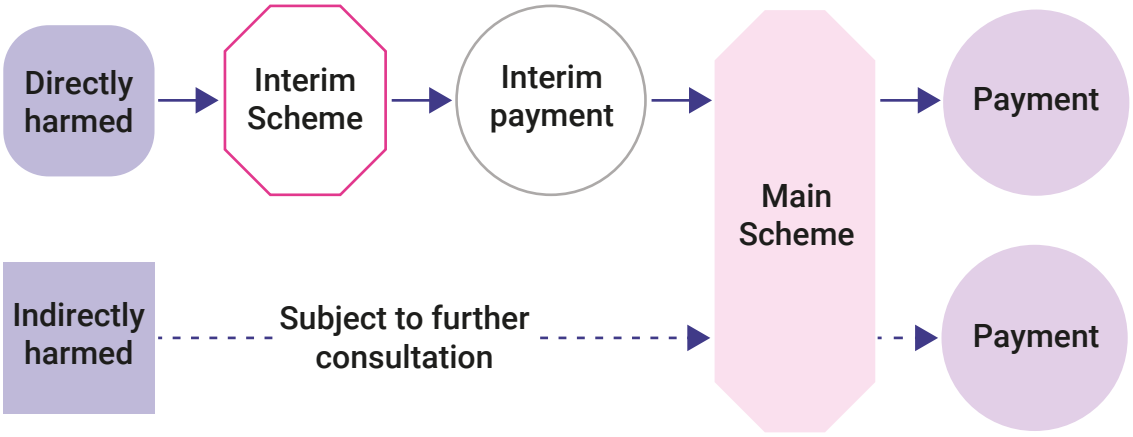
Infographic 2A: A one-stage process for redress: a single, Main Scheme



231. This approach is not as straightforward as it appears. The failure of the healthcare system to record sufficient data means there are well recognised difficulties in estimating the number of patients harmed which will make cost estimates of the Main Scheme difficult. This may result in substantial delays in any scheme being approved and making payments. Therefore, the Commissioner does not recommend this approach.

232. The Commissioner recommends that ministers pursue a two-stage approach.

Infographic 2B: A two-stage process for redress: an Interim Scheme and a Main Scheme



Recommendation 3

The government should create a two-stage financial redress scheme comprising an Interim Scheme and a Main Scheme.

233. The Interim Scheme will be easily accessible for claimants and will result in the award of an interim payment to those directly harmed. The purpose of the Interim Scheme is to offer patients an initial, fixed sum in recognition of the avoidable harm they have suffered as a result of system-wide healthcare and regulatory failures.

234. The Main Scheme will involve an individualised approach with more stringent evidential requirements that will require time to develop. Payments from the Main Scheme should be more comprehensive and designed to help meet the needs of those who have been harmed. There should also be scope within the Main Scheme to award redress to those indirectly harmed, which is another issue that requires careful consideration. The purpose of the Main Scheme is to recognise that the system-wide healthcare and regulatory failures caused different levels of harm to each patient.

235. This approach has clear advantages. The Interim Scheme, providing a standardised payment, will provide some much-needed prompt financial assistance for harmed patients. We anticipate that the Interim Scheme would be able to make awards in 2025 – as set out in our Recommendation 4.

236. Crucially, it will facilitate a more accurate assessment of the number of potential claimants and the severity of the harm they have suffered before establishing the Main Scheme. The primary means the government will have to assess numbers is via a process known as 'impact assessments'. This approach draws on examples of two-stage schemes used by the vCJD Trust, Scotland's Redress Scheme and the interim payment under the Infected Blood Scheme.[133, 134] It helps address the tension between a fully individualised scheme and fully standardised scheme by combining elements of both.

237. We are also pleased to say that 70% of respondents to our redress survey agreed with this two-stage proposal, with only 4% disagreeing and 26% stating that they did not know.

Overall eligibility criteria

238. This section covers concepts and eligibility criteria that are relevant and applicable to both stages of the scheme.

Infographic 3: Elements of the overall eligibility criteria

*** =subject to discussions with devolved administrations**

Directly harmed

239. The terms of reference for this work state that our options are to cover 'those harmed' by pelvic mesh and valproate. This clearly includes those who have been 'directly harmed'. We consider a useful definition of this term to be:

- individuals whose mothers were taking valproate at any point during their pregnancy
- patients who have been implanted with pelvic mesh to support pelvic organs for the treatment of SUI or POP

240. These definitions match those of the First Do No Harm review.[135] This is important to ensure that the scope of our proposed redress scheme aligns with the extent of healthcare failures that the First Do No Harm review identified.

241. With regards to the definition of directly harmed by valproate covered in the first bullet, we are aware that this excludes individuals whose fathers were taking valproate at the time of conception and/or the children of those harmed by valproate exposure (to cover inter-generational effects). Patients raised both these issues with us. However, research is ongoing into both, and there is genuine uncertainty among clinicians about these issues, so it is not yet possible to draw definite conclusions.[136]

242. Once the clinical position is clearer, further work would be required to establish whether there have been healthcare failures in relation to these two groups. If failures do emerge, separate discussions would be needed about redress.

243. With regards the definition of those directly harmed by pelvic mesh in the second bullet, we know that it is important to explain the application of this definition to those patients treated with rectopexy mesh.

244. Rectopexy mesh can be used to treat two main conditions:

- male and female patients with rectal prolapse
- female patients with a rectocele (also known as posterior vaginal prolapse)

245. Patients treated with rectopexy mesh for rectal prolapse do not fall within the proposed definition of 'directly harmed' above. This is because rectal prolapse does not fall within the definition of POP that we and the First Do No Harm review adopted – namely a pelvic organ bulging into the vagina.[137] This definition also prevented us from making recommendations in relation to hernia mesh, despite hearing from patients about their negative experiences.[138]

246. However, this is not to dismiss the very real concerns that patients have raised with us about the harm caused by other uses of mesh and which, in many instances, the Commissioner shares. The government needs to set out to patients how it proposes to investigate these issues going forward in a way that listens, and responds to, the experiences of these groups of patients.

Indirectly harmed

247. The harm caused by these interventions clearly extends beyond those who have been directly harmed, as defined above. The psychological, emotional and, in many cases, physical impacts on friends, families and loved ones should not be underestimated. We refer to these people as those who have been 'indirectly harmed'.

248. The impact on indirectly harmed individuals was clear in our engagement with both valproate and mesh injured patients:

> **"It is hard enough to live your life suffering with epilepsy… But if you add to epilepsy having to look after a child with this condition… you really are doubly injured." (Mother of a valproate harmed patient)**

> **"Families have completely broken down because of the stress of dealing with children who need help." (Valproate patient representative organisation)**

> **"My husband has taken on most of the roles, I'd much sooner be able to do things myself." (Mesh injured patient)**

249. From engagement with patients, we believe there would be consensus on including the categories of spouses, civil partners and long-term cohabitees as well as parents and children (whether biological or adopted formally or informally) within a core category of indirectly harmed individuals. In addition, it would seem sensible to consider a discretionary category of people who can demonstrate a compelling reason to be classified as eligible.

250. However, as Sir Robert Francis KC referenced, it is advisable for government to place some limits on the classes of relationship included in the definition of indirectly harmed to make any scheme workable.[139] This work needs to be undertaken carefully once the final details of redress have been decided upon and in conjunction with the harmed patients. Without these details, it is hard for patients to currently form a view on this issue, as our survey results illustrate.[140]

251. Consequently, we suggest that, given the importance of setting up the Interim Scheme quickly, the pool of eligible applicants for the Interim Scheme is confined to those directly harmed only. Provision could then be made within the Main Scheme for those indirectly harmed once defined.

Recommendation 4

The Interim Scheme should award directly harmed patients a fixed sum by way of financial redress. These payments should start during 2025.

Recommendation 5

The Interim Scheme should be followed by a Main Scheme. This would offer more bespoke financial support to directly harmed patients based on their individual circumstances and – subject to further consultation on definitions – those indirectly harmed.

Eligibility for the estates of those deceased

252. Where a directly or indirectly harmed individual who would have met the applicable eligible criteria has died, the government needs to consider allowing the personal representatives of a deceased person's estate to apply for an award on their behalf.

253. For the Interim Scheme, these considerations should be relatively straightforward as the interim payment is a fixed amount. The government will need to work with its legal representatives with the Main Scheme, where the more individualised nature of the potential financial awards needs to be considered.

Determining the providers in scope

254. Considering the evidence on this subject, which makes clear that avoidable harm occurred in both NHS and private providers, we make the following recommendation:

Recommendation 6

Patients who received relevant treatment through either the NHS or independent sector should be eligible for the Interim Scheme and Main Scheme.

Place of harm and patient's place of residence

255. In chapter 1, we discussed the tension between the Commissioner's England-only statutory remit and the fact that patients have been harmed across the UK.

256. Subject to DHSC's discussions with devolved administrations, we believe that it would be sensible to consider how to impose a residency requirement such that a person must have been resident in England (or, subject to those discussions, the UK) at the time of the relevant treatment that caused the harm.

257. It would also be sensible to consider how to impose a requirement stating that eligibility for both valproate and pelvic mesh redress should be restricted to those treated in England (or, again, subject to those discussions, the UK) at the time the harm to the directly harmed person was caused. Exemptions will be required in circumstances where the treatment abroad was paid for by the NHS.

Chapter 5:

Operational issues for a redress scheme for pelvic mesh and valproate

> "I worry about her future as she would one day like to live away from home... If I had known what I was doing when I was taking the drug, then I would not have brought my children into the world simply because they are so, so unhappy and they will never be OK."
>
> (Mother of a child with FVSD)

> "It's heart breaking, as I was told that the mesh was the best thing for my prolapse, and that my quality of life would be much improved in having it done, [I was] never told of any possible complications, and I trusted fully all I was told. Instead, it has ruined my life in every way."
>
> (Mesh harmed patient)

Operation of the Interim Scheme

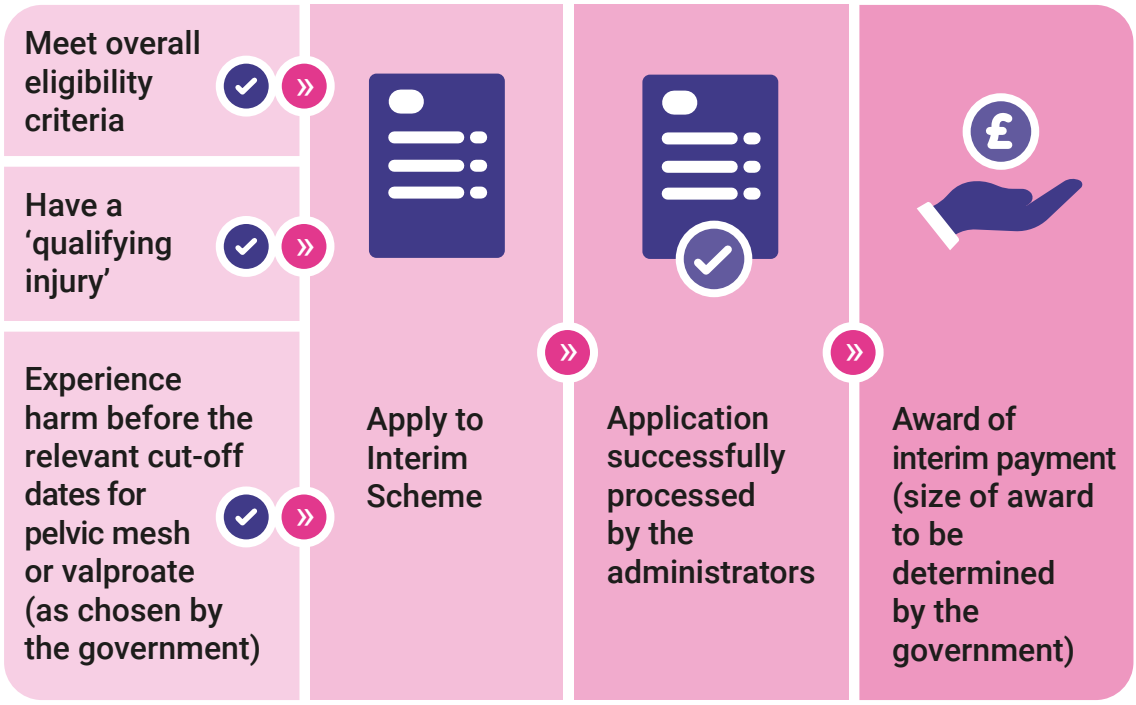
Summary

- In addition to meeting the overall eligibility criteria for the redress scheme, there will need to be a clear set of additional eligibility criteria specific to the Interim Scheme. These are:
  - cut-off dates for mesh and valproate so that only patients who received treatment by a specific date should be eligible for an interim payment – we recommend a number of dates, justified with reference to developments that should have made the use of both products safer from a patient perspective
  - patients must have suffered a 'qualifying injury' – we have suggested that further work is undertaken with multidisciplinary panels and patients to establish broad criteria for such injuries
- The application process should be made largely paper-based, using existing medical records.
- We discuss how much patients told us the interim payment should be – with figures ranging from £20,000 to over £340,000. Given the Commissioner's role and remit, we wanted to amplify the voices of patients on this topic, rather than make a proposal ourselves. The median figure from our survey was £25,000.
- The Interim Scheme is intended to be a stepping stone to the creation of the Main Scheme.

258. In addition to meeting the overall eligibility criteria for the redress scheme, there will need to be additional eligibility criteria for directly harmed individuals specific to the Interim Scheme.

259. Eligibility for an Interim Scheme needs to be composed of various different elements, summarised in infographic 4.

Infographic 4: Operation of the Interim Scheme – patient journey



Define the period during which the person was harmed: pelvic mesh cut-off dates

260. We recommend that any patient who had any of the following types of pelvic mesh implantation surgery within these timeframes should be eligible for an interim payment under the Interim Scheme.[141] These dates are intended to be a starting point for ministers, but we recommend they undertake further work on them alongside patients to test and – if necessary – refine them.

- Trans-vaginally inserted POP pelvic mesh implanted before the change in the NICE guidance on 15 December 2017.[142] After this date, trans-vaginally implanted POP mesh should only have been inserted on a 'research only' basis.
- Trans-vaginally inserted mesh for the treatment of SUI implanted before the start of the NHS England pause on 11 July 2018.[143] All SUI mesh inserted after this date should have been under a high vigilance regime.
- Trans-abdominally inserted pelvic mesh for POP has never been subject to a high vigilance regime. Without establishing any cut-off date, there are (at least) two options that ministers could consider using.

- 2 April 2019 (or any date after) – when updated NICE guidance was published on POP in women. This guidance included NICE patient decision aids to support patients and should have raised awareness of the potential complications with patients and clinicians. However, the government would need to be confident that the decision aids were being used.
- 1 August 2020 (or any date after). This date follows the closure of the First Do No Harm review on 31 July 2020.[144] The publication of the report, and the widespread publicity around it, should have raised public and professional awareness of the potential risks of pelvic mesh.

Define the period during which the person was harmed: valproate cut-off dates

261. We acknowledge that the launch of the Pregnancy Prevention Programme in March 2018 is the key external event in this area.[145] Based on this launch, the below dates are options for ministers to consider.
    - A date of birth before 23 June 2019 (43 weeks from the 25 September 2018 when MHRA has said that it felt that health professionals had had sufficient time to comply with the requirements of the Pregnancy Prevention Programme.[146]
    - A date of birth before 22 May 2021 (43 weeks from the close of the First Do No Harm review, for the same reason as set out above in relation to pelvic mesh).
    - Postponing the setting of a cut-off date for the Interim Scheme until the valproate registry demonstrates that ongoing harm has stopped (with a backstop date of the Interim Scheme's closure date).

262. If the third option is not chosen by ministers for the Interim Scheme, we suggest that the Main Scheme be given a discretionary power to dispense with cut-off dates where appropriate – so that, for example, those who suffer avoidable harm from taking valproate in pregnancy in 2023 are eligible.[147]

Define qualifying injuries

263. In addition to meeting the time periods set out above, we envisage that a person must have a 'qualifying injury' to access the Interim Scheme. Given that the purpose of the Interim Scheme is not to quantify the level of harm caused or the severity of the ongoing consequences of such harm, 'qualifying injuries' should be broadly defined.

264. The precise definition of qualifying injuries is outside of the terms of reference for this report and will need to be created by a multidisciplinary expert group for both pelvic mesh and valproate, drawing on international comparisons. We will confine our comments to two key points.

- Valproate injury, unlike pelvic mesh complications, has a standalone disorder recognised under the ICD-11 (namely FVSD) with observable traits, so a qualifying injury should be presumed for those with such a diagnosis. Given patients' concerns about significant under-diagnosis of FVSD, and the lack of specialists in this area, we think that those without a formal FVSD diagnosis but who can demonstrate known characteristics of FVSD (along with valproate exposure in pregnancy) should also be classed as having a qualifying injury. This is particularly important given that we understand clinicians are seeing effects in low dose-exposed children, who are less likely to have a diagnosis.[148]
- England is not the only country to grapple with these issues. New Zealand's Accident Compensation Corporation has produced guidance on physical injuries which are likely to be accepted, those which might be accepted and those which are unlikely to be accepted for both pelvic mesh and valproate harm.[149] We would support the use of both the content and structure of the New Zealand advice as a starting point for any Interim Scheme. Such an approach is accessible and promotes transparency. However, for valproate, any guidance must include neurodevelopmental harm. For pelvic mesh, injuries should be construed widely. For example, infection should not be restricted to infections associated with the operation itself but should also include recurrent urinary tract infections, as well as pain on sexual intercourse (dyspareunia).

Application process

265. Establishing eligibility for interim payments should be a paper-based exercise, mainly using existing medical records. To do this, the patient (or their authorised representative) will need to sign an authority for the scheme to access their medical records, which the scheme will then use to establish if they meet the eligibility criteria.[150]

266. For valproate, for example, there would need to be some evidence that the individual's mother took valproate during their pregnancy, so that they fall within the definition of directly harmed.

267. There will be situations where there are difficulties in getting medical records. Valproate requires that the affected individual has access to their mother's medical records rather than their own, which could be difficult if a mother is unwilling or unable to provide her records. The government will also need to consider the issue of records that pre-date the start of the Access to Health Records Act 1990.[151] There may also be more unique cases, such as adoption or family migration, or where records have simply been lost.

268. We would expect any redress scheme to have caseworkers available to assist people who face difficulties in getting records – as the Redress Scotland Scheme does via its Redress Support Service.[152] We would also expect the scheme to develop a pragmatic approach in cases where medical records cannot be found, underpinned by a presumption of truth as set out below.

269. A review by a qualified caseworker overseen by a clinical team of a patient's medical records, application form and other supporting documents should in the majority of cases be sufficient for that caseworker to make a decision about eligibility.

270. Once in possession of these documents, ordinarily, we can see no need for additional interviews, intimate medical examinations or further diagnostic tests. However, these could be required where just and necessary to do so. Where necessary, diagnostic tests such as MRIs to support a pelvic mesh claim could be procured privately to help speed up the process.

271. A frequent issue encountered by patients who have sought to access compensation through legal means is causation – proving that the injury they have was caused by pelvic mesh and/or valproate and not the responsibility of something or somebody else. Therefore, once a qualifying injury is established and the rest of the eligibility criteria are fulfilled, it should be presumed that the pelvic mesh or valproate caused the qualifying injury or injuries.

272. A fair and inclusive application process on paper is not sufficient to honour the 'respect for dignity' principle. The culture underpinning the scheme and implementing the processes must be supportive, respectful and restorative. The mistakes of the Macfarlane Trust, a company providing ex gratia payments to those infected with HIV from contaminated blood, should never be repeated.[153] As one mesh injured patient said: "The biggest thing missing in all of this is empathy."

Quantum of interim payment

273. Like with all financial remedies (whether through a redress scheme or litigation), no sum of money can ever turn back the clock. But we would hope that a not insignificant sum of financial redress through the Interim Scheme would provide some immediate support to patients.

274. Given the Commissioner's role and remit, we wanted to relay to ministers what amount patients think would be appropriate. These figures are set out in the table below.

Response stated to be about which intervention	Median quantum for an interim payment	Mean quantum for an interim payment
Pelvic mesh	£20,000	£139,556
Valproate	£100,000	£340,907
Combined pelvic mesh and valproate responses	£25,000	£167,553

275. In responses to our survey, patients said they chose the figures that produced these averages for various reasons. Many said it represented all, or a percentage, of their past financial losses whether for home adaptions, incontinence aids, travel or lost earnings. Others said that they had attempted to place a financial value on their pain and suffering.

276. Generally, patients thought of the Interim Scheme as representing redress for past harm and saw the Main Scheme as supporting their future needs.

Duration

277. The Interim Scheme is intended to be a stepping stone to the creation of the Main Scheme. It is likely that it could be wound down when the Main Scheme is established (as with the interim vCJD Trusts following establishment of the Main Trust).

278. The precise length of time it is open would be for the government to decide, but a period of 12 to 18 months following launch would seem sensible.[154] Applicants who came forward after this time would still be eligible to apply for the Main Scheme, as set out below.

Operation of the Main Scheme

Summary

- There will be a number of routes to apply for the Main Scheme for injured patients. The largest group will be those patients who received an award through the Interim Scheme.
- Unlike the Interim Scheme, there is a strong case for a greater degree of discretion in eligibility for the Main Scheme. This discretion would be most commonly used to allow directly harmed patients entry into the Main Scheme who did not meet cut-off dates (if chosen by the government).
- Awards via the Main Scheme would be more individualised and for 'qualifying injuries'.
- A multidisciplinary panel of experts in the relevant fields will be required to devise the criteria around type and severity of injury for both pelvic mesh and valproate.
- Ministers will need to consider what types of losses the financial award under the Main Scheme is designed to cover.
- This decision will then need to be followed by a decision on how to quantify the losses that ministers want the Main Scheme to cover.
- We suggest that these decisions are deferred until the Interim Scheme is set up and can provide greater evidence of the size of the harmed populations, and the extent of their harm.

279. There will be a number of routes to apply for the Main Scheme for injured patients. The largest group will be those patients who received an award through the Interim Scheme. Patients who received an interim payment should only be required to provide evidence for any new eligibility requirements of the Main Scheme, rather than being made to start again. This process should be seamless and non-onerous, and patients should not have to re-register or fill in further application forms with their personal details.

280. People who have not received a payment through the Interim Scheme, but who wish to apply to the Main Scheme, will fall into at least one of four categories (and some into multiple):

- those who chose not to apply to the Interim Scheme
- those who missed the closing date for the Interim Scheme

- those indirectly harmed (subject to further consultation and the government's final decision on this point)
- those who were ineligible for the Interim Scheme when it was open, but who now wish to ask the administrators of the Main Scheme to exercise their discretion to make an award

281. Anyone in these categories would need to apply to the Main Scheme.

Discretionary eligibility: in detail

282. Unlike the Interim Scheme, there is a strong case for a greater degree of discretion in eligibility for the Main Scheme. On this, we have been influenced by our discussion with the Thalidomide Trust whose founding documents somewhat restricted their discretion, making it harder for them to adapt when new research emerges or beneficiaries' needs develop.

283. We cannot exhaustively set out the circumstances where this discretion may be useful for the administrators to exercise. Should the government choose cut-off dates for the Interim Scheme for both pelvic mesh and/or valproate, this discretion would be most commonly used to allow directly harmed patients entry into the Main Scheme who did not meet those dates, but can demonstrate a compelling reason to be included. For example:

- those with a diagnosis of an eligible pelvic mesh injury but whose pelvic mesh implantation surgery falls outside the dates required for an interim payment – if the patient can demonstrate it is more likely than not that the information provided to them before surgery was not sufficient to allow them to make an informed decision, their application should be accepted by the Main Scheme
- those harmed by valproate with an eligible injury, but whose date of birth is on or after the chosen cut-off date for an interim payment – if the patient can demonstrate it is more likely than not that their mother took valproate during pregnancy and that the requirements in place over prescribing valproate at the time of the pregnancy were not complied with

Eligible injuries

284. In the Main Scheme we talk of 'eligible injuries' regarding pelvic mesh and valproate. The definition of eligible injuries is likely to be different to the definition of qualifying injuries used by the Interim Scheme described above.

285. This is because the Interim Scheme will provide a fixed payment to all patients who have been injured by the failures of the healthcare and regulatory systems. However, the Main Scheme is intended to provide a more personalised contribution towards meeting individual needs – needs which are usually correlated to injury severity.

286. This will require the development of a more detailed definition and grading of injuries in the Main Scheme than the Interim Scheme. This process must be done by a multidisciplinary panel of experts in the relevant fields, alongside harmed patients. Once the diagnosis and assessment guidance document are produced by the panel, a broader range of people can then be involved in applying them. This will mitigate the time commitment needed from the relatively small pool of expert clinicians, particularly with regards to FVSD.

Categories of loss

287. Ministers will need to consider what types of losses the financial award under the Main Scheme is designed to cover. They will also need to decide how to quantify those losses.

288. The first option for ministers would be to decide that the awards under the Main Scheme will cover all the categories of loss covered by a court award of damages – the 'litigation model'. This court award is split into two, covering a broad category of losses designed to place the claimant in the position they would have been had the harm not occurred.[155]

- General damages – compensation for the pain, suffering, loss of amenity, loss of enjoyment (for example, being unable to go on holiday), loss of use (for example no longer being able to drive a vehicle) and other losses which do not have an inherent financial value.
- Special damages – compensation for the economic impact of the injury, including past losses (expenses which have been incurred) and future losses (expenses that will need to be incurred in the future because of the injury). This category includes the costs of home adaptions, loss of earnings, care costs and a sum for the cost of medical care, because the court is required to disregard the availability of NHS care.[156]

289. However, the flexibility of redress schemes means that the Main Scheme would not have to provide financial redress for every category of loss that a court award of damages covers. This is reflected in the 'broad' key principle that we cited with approval at the start of chapter 4.

290. In addition, there are numerous examples of countries adopting different approaches when it comes to the categories of losses that their redress schemes cover. A selection of these is summarised in the table below. Any of these examples could form the basis of an option that ministers decide on in relation to this decision. None of those listed below adopt the 'full litigation' model.

Example	Categories of loss covered
New Zealand	When New Zealand moved away from medical negligence litigation in the 1970s, it moved from full compensation to the principle of 'fair compensation'. Fair compensation provides lower value awards but was available to a wider number of people and this was considered to be fairer overall than the 'compensation lottery' of litigation. In New Zealand, the main compensation entitlements under what it terms 'fair compensation' are: • rehabilitation costs • weekly compensation to cover lost earnings • lump sum compensation for permanent impairment, intended to cover non-economic losses In the case of a death, various forms of redress are available including: • funeral grants • survivors' grants • payments for dependants, including help with childcare costs
Vaccine Damage Scheme (UK)	N/A – a fixed, global sum would not need to specify what it is being awarded for.

Example	Categories of loss covered
Armed Forces Compensation Scheme (UK)	Payments made under the Armed Forces Compensation Scheme (which provides payments for individuals injured while serving in the Armed Forces) pays the following categories of redress: • lump sum payments (these cover non-economic losses) • loss of earning payments • independence payments equivalent to PIP In the case of a death, various forms of redress are available including: • survivors' guaranteed income payments – to compensate for the deceased's loss of earnings • child payments – to compensate for the deceased's loss of earnings • bereavement grants – to offset the difference between death in service lump sum payments between the two Armed Forces pension schemes
Scandinavia	The following categories of loss covered are consistent across Sweden, Denmark, Norway and Finland: • permanent harm • loss of earnings both past and future • medical expenses • incurred economic losses Where an affected individual has died due to the impact of their injury: • funeral expenses • loss of maintenance paid to survivors
Hybrid	A combination from any of the above approaches.

291. Our patient engagement survey explored some of the patients' initial views on this subject. It asked them to rank various categories of loss from the most important to the least important. The results revealed the most important category was financial redress for pain and suffering caused by the harm (62%). The second most important category chosen was financial redress for the injustice caused by the lack of information (25%). Full details of the patient engagement survey are in annex E.

292. There was some divergence between valproate and pelvic mesh respondents. The 62% figure cited above was among all respondents. However, this figure fell to 35% among those valproate respondents only. While we cannot be sure what is behind this difference, it may be that the neurodevelopmental harms associated with FVSD generate different needs to those harmed by the constant physical pain of pelvic mesh.

293. In addition, we heard from our meetings with patients that the issue of buying a house and access to suitable travel support was important for valproate harmed families, while loss of pension entitlement was a particular worry for mesh harmed patients. As a result, further patient engagement is needed on this subject.

Quantifying the losses

294. Once it has been agreed what categories of loss the Main Scheme payment should cover, ministers will need to decide on the mechanism for quantifying those losses. There are several ways in which losses under each category can be quantified.

295. We recommend that once the Interim Scheme has provided greater information on the size of the harmed population and the severity of injury, the government revisits with patients what would be the best quantification option for each category of loss it wants to cover. Data from the Interim Scheme on the size of the harmed population will help quantify the costs of the different quantification options for each category, and help support a revised impact assessment.

296. We acknowledge that quantification under the Main Scheme may result in awards less than court awarded damages and which, therefore, only represent a contribution towards the losses people have suffered.

297. But redress is different to compensation through litigation – and for good reason. By providing an easier, less stressful, and non-adversarial route for patients to access, such schemes do not try to match how a court would award financial damages.

298. In addition, it is common for a financial award made through 'without liability' out-of-court settlements to be lower than an award made to an individual who succeeded in litigation. Litigation is inherently risky and lower settlement figures recognise this fact. A redress scheme is likely similar to this position given the benefits that it offers over traditional litigation.

Option	Explanation	Advantages	Disadvantages	Example
Full litigation compensation	• Quantification is designed to put the person back in the position that they would have been before the injury • The Law Reform (Personal Injuries) Act 1948 requires the court to disregard the availability of NHS care when calculating damages	• Parity with litigants • Payments reflect the severity of the harm suffered	• Complex to quantify • Slow and costly to administer due to individual quantification • Some legal rules present challenges for some claimants – for example, those self-employed • Limited by litigation categories – for example, excludes most indirectly affected individuals	• Courts in England and Wales in a product liability or clinical negligence case

Option	Explanation	Advantages	Disadvantages	Example
Tariff based	• Redress can be quantified using a tariff-based approach • A tariff-based approach for compensation for pain and suffering (one of its most common uses) would involve a multidisciplinary panel working with patients to devise a table of injuries associated with valproate and pelvic mesh harm • Each of these injuries would then be assigned a tariff level representing the severity of harm • Each tariff level would then be associated with a lump sum amount of financial redress	• Simple to administer • If the tariff is generous, awards can provide parity with litigation • Can include awards not available under litigation • Patients often cited, with approval, the Armed Forces Compensation Scheme	• If the tariff is restrictive, awards can be less generous than litigation	• Armed Forces Compensation Scheme (UK)

Option	Explanation	Advantages	Disadvantages	Example
Fixed sum	• A fixed sum approach is the same sum awarded to everyone regardless of individual circumstances or needs	• Simple to administer • Expenditure per person is known from outset • Pelvic mesh patients generally expressed a preference for this approach	• Payments do not reflect the severity of the harm suffered • Valproate families often expressed support for more individualised-style support based on need – with frequent references to the operation of the Thalidomide Trust (which uses this model)	• More often used for interim payments – for example, the infected blood interim payment.

Option	Explanation	Advantages	Disadvantages	Example
Top-up model	• The quantification of payments under the top-up model is designed to cover the cost of additional needs rather than the costs of services which are available free of charge through the state (within the UK context this would include NHS care, for example) • It also considers additional state financial support, such as social security benefits • For example, the quantification of loss of earnings under the top-up model would be based on a notional annual salary, discounted by the amount of Universal Credit available – reference would not be made to an individual's actual salary • In such a system, there would need to be consensus on what the figure for the notional salary is	• Simple to administer • Can include awards not available under litigation	• No parity with litigants in the UK • Depending on where the bars are set for things such as notional salary, this option can be less generous than other options • Relies on the adequacy of state provision of social care/ healthcare and social security benefits	• Scandinavian countries

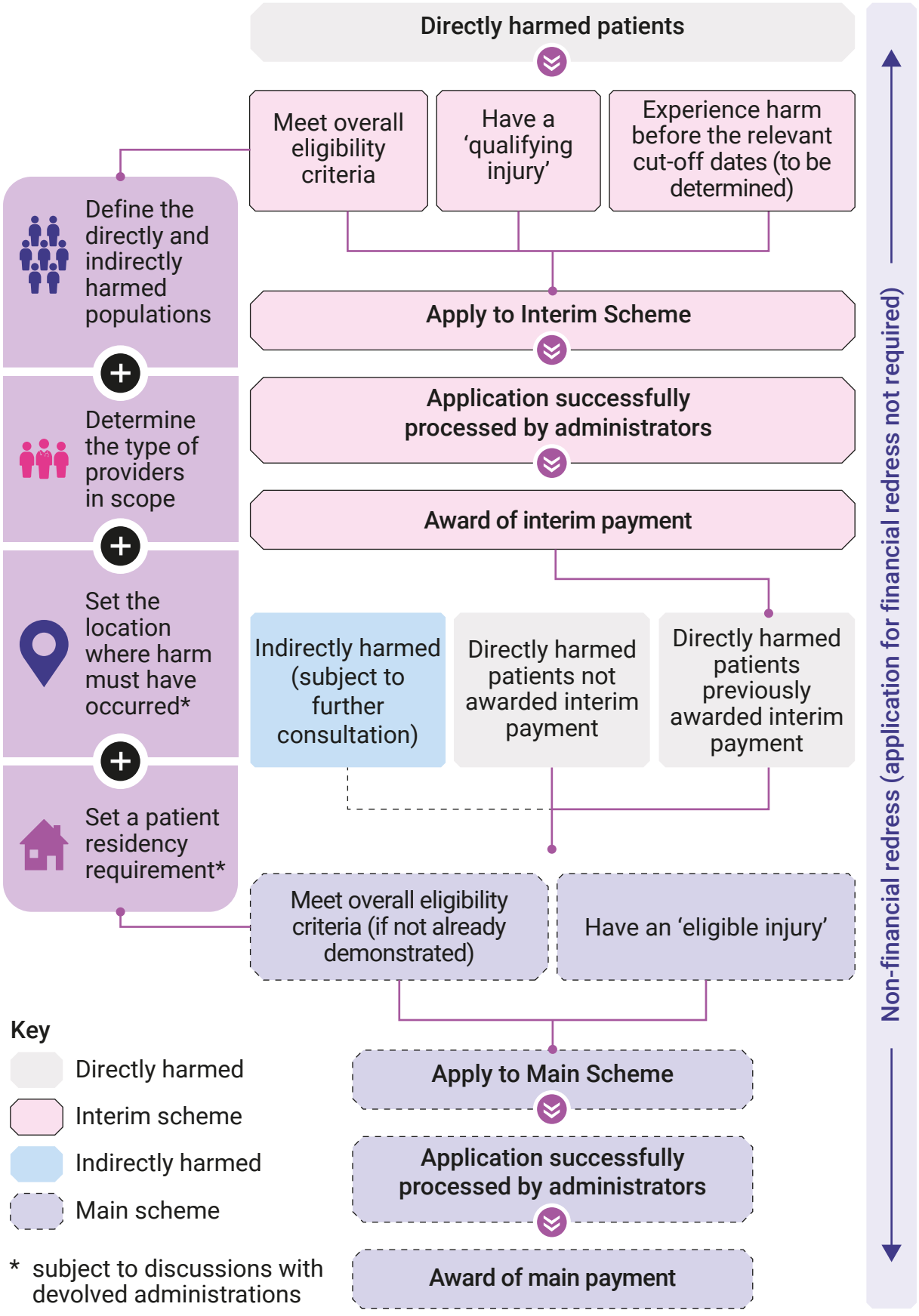
Option	Explanation	Advantages	Disadvantages	Example
Hybrid	• A combination of the above – with different quantification options for different categories of loss, or multiple quantification options for within one category of loss	• Flexible and can adapt • Most claims handled promptly and efficiently • If the tariff is generous, awards can provide parity with litigation • Can include awards not available under litigation	• Less straightforward to administer • Potentially more difficult to understand	• The 9/11 Victim Compensation Fund used a tariff-based approach to loss of earnings (track A), with the option for claimants to seek a hearing with a special master to explain why the tariff was not appropriate in this case and an individualised litigation style assessment should be used instead (track B) • Similarly, the vCJD Trust administers funds on a tariff basis from its Main Trust, with additional more needs-based payments made from its Discretionary Trust • Redress Scotland

Option	Explanation	Advantages	Disadvantages	Example
Demonstrating charitable need	• An affected individual is required to demonstrate charitable need • This approach has been used by charities – including the infected blood charities which predated the current support arrangements		• This approach was hugely unpopular and was described as 'the worst form of modern-day begging'	• Original infected blood arrangements

The overall proposal

299. In chapters 4 and 5, we have discussed the key elements of the redress proposals for those harmed by pelvic mesh and valproate. The overall scheme that we recommend is illustrated by infographic 5, on the following page.

Infographic 5: Redress for pelvic mesh and valproate: the overall proposal



Operational issues covering both the Interim Scheme and Main Scheme

Summary

- We recommend embedding a presumption of truth into both the Interim Scheme and the Main Scheme to support the overriding principle of respect for dignity and ease of proof.
- There are a number of potential options for the scheme administrator, and this list is not exhaustive. We leave the final decision to the government.
- However, we do think that there are number of options which are not suitable because they would not command the support of patients, DHSC or any of the bodies that it sponsors.
- There are several options for holding funds to provide redress:
  - the administrator holds the funds and makes the payments
  - the administrator makes recommendations for payments which are then paid on an ongoing basis via a pre-determined source of funding
- A government department acts as the administrator.
- There are a number of miscellaneous, but important issues, for ministers to address:
  - a number of those directly harmed by exposure to valproate will lack mental capacity
  - the degree of support that the Interim Scheme and Main Scheme provides those seeking redress – in terms of legal and emotional support
  - capitalised (one-off) or periodic payments
- Extreme care needs to be taken by the government when considering how payments from the redress scheme interact with taxation, social security and other benefits such as educational support. Patients should not lose out because of any financial awards made by a redress scheme.

Application processes

300. The process for establishing eligibility through any redress scheme must not be overly onerous on the patient – they have been through enough already. Such an approach comes back to meeting the 'procedural' justice needs of patients that we referred to in chapter 1, and the 'ease of proof' and 'respect for dignity' key principles described at the start of chapter 4. Many patients described the exhaustion associated with repeatedly having to prove themselves and constantly reliving their trauma. As one mesh injured patient said:

> **"It [redress] should not be something that these patients have to bend over backwards to prove... because that's the biggest thing in all of this… having to prove [for example] that you need your husband to wipe your backside for you… it is so degrading."**

301. As an overriding principle, and to build trust that has been so broken, we recommend embedding a presumption of truth into both the Interim Scheme and the Main Scheme, based on an equivalent provision in a Scottish redress scheme for survivors of sexual abuse called (Redress Scotland):

> **"In determining an application, the panel is to start with the presumption that any information provided by the applicant in respect of the application is true and accurate to the best of the applicant's knowledge and belief."**[157]

302. The presumption does not mean that patients can successfully apply with no evidence. It acknowledges that in these two cases – because of the history of gaslighting and patients not being believed – patients' experiences need to be presumed true and accurate to the best of the applicant's knowledge and belief. In our view, such a presumption 'levels the epistemic justice playing field' between patients and the evidence provided by clinicians – who often, knowingly or unknowingly, already benefit from such a presumption in their favour.

Recommendation 7

Patients should find the application process for both the Interim Scheme and the Main Scheme straightforward, accessible, and non-adversarial. To support this, a presumption of truth should be embedded within the scheme, which would apply when assessing the evidence provided by patients to meet the eligibility criteria.

Appointment of administrator

303. There are a number of potential options for the scheme administrator, and we think it is appropriate to leave the final decision to the government. However, the Commissioner does think that there are some unsuitable options that would not carry the support of patients – based on her knowledge of similar schemes and what patients have told us. 85.9% of respondents to our survey agreed or strongly agreed with the statement that 'any redress scheme should be run by a new body independent from government or the NHS'.

Option 1 – DHSC

304. Based on patient feedback, DHSC should not administer these redress schemes. Considerable dissatisfaction with procedural issues has been expressed about the Windrush Compensation Scheme, which is run by the Home Office.[158] More fundamental concerns rest in the lack of independence of a scheme where eligibility and quantum are judged by the body responsible for the initial injustice. We cannot risk this situation happening again.

Option 2 – an existing DHSC sponsored arm's length body

305. An arm's length body of DHSC is another option for scheme administrator. In this category, there are two possible candidates: NHS Resolution, and the NHS Business Services Authority (NHSBSA). Again, we do not think that such a body would command the support of patients, and therefore should not be chosen.

306. NHS Resolution deals with claims for compensation on behalf of the NHS in England in accordance with the law of negligence. This includes meeting liabilities arising from valproate and pelvic mesh claims made against the NHS when they are due.[159] In our view, this role disqualifies it from administering valproate and pelvic mesh redress schemes. It is not sufficiently independent and there are obvious conflicts of interest, both perceived and actual, in asking a single organisation to act both on behalf of the legal defendant in any litigation and to be the decision maker in a redress scheme.

307. The NHSBSA provides a number of support services to the NHS and DHSC in England, including prescription services and student grants. As part of these services, it already administers the England Infected Blood Support Scheme and vaccine damage payments.[160] But we have concerns with the capacity and expertise of the NHSBSA to handle additional claims under this redress scheme.[161]

Option 3 – a charitable trust

308. A trust could be established. This was the preferred vehicle for the Thalidomide Trust (at least initially) and the vCJD Trust. It is a tried and tested approach and was positively referenced by a number of patients.

309. The trust is overseen by trustees on a trust board, who set strategic direction and oversight. Day-to-day decisions can then be taken by staff members headed by a chief executive.

310. We acknowledge that a trust requires upfront funding to some degree or other and can be more expensive to run (depending on the precise format of the management of the trust).

Option 4 – a limited company

311. Limited companies have been used by the government to administer redress, such as the infected blood companies. The advantages of creating a charitable company limited by guarantee – registered with both Companies House and the Charity Commission – was also cited by patients. It combines many of the features of a charitable trust with the benefit of less onerous personal liability of trustees.

312. There is nothing fundamentally wrong with this approach, but it can be difficult to ensure that the company is sufficiently independent. The Skipton Fund Ltd and MEET Ltd were essentially subsidiary companies created and funded by DHSC.

Option 5 – a new redress arm's length body

313. In his report about infected blood compensation, Sir Robert Francis KC recommended creating a new, independent arm's length body to administer his proposed framework.[162] There could be a new, unified arm's length body which administers the separate schemes for valproate, pelvic mesh and infected blood payments under one roof. This option also has overlap with Recommendation 3 of the First Do No Harm review – discussed in chapter 2 – and where we explained that the government has consistently rejected this recommendation.

314. However, the recent amendment passed as part of the Victims and Prisoners Bill presents an opportunity for the government to reconsider. New Clause 27 requires the government to establish a new body to administer a compensation scheme for victims of the infected blood scandal.[163] A new body created for infected blood could also be used to administer redress for pelvic mesh and valproate – provided it has sufficient capacity and expertise for both sets of redress. We hope that the government gives serious consideration to this option.

Conclusion

315. This is not an exhaustive list and there may be other options for the administrator which the government would like to consider. We acknowledge that there is a balance to be struck between speed of award and creation of wholly new processes and structures.

316. The Commissioner leaves the final decision to the government but has decided to make a broader recommendation on this subject as set out below. Whatever administrator is chosen, they need have a line of accountability into Parliament via the Public Accounts Select Committee given the public expenditure involved. This will help to ensure that the administrator is independent and has sufficient expertise and resources to fulfil its functions.

Recommendation 8

Both the Interim Scheme and the Main Scheme should be administered by an independent body which commands the confidence of patients.

Mechanism for administrator to hold funds

317. The source of funding may impact on the way scheme funds are administered and held.

Option 1 – the administrator holds the funds and makes the payments

318. This model is commonly used in litigation. For example, NHS Resolution collects funds from the organisations it covers. The Thalidomide Trust funds come from contributions made by the distributors of thalidomide and their successor companies as well as DHSC..

319. This approach requires the responsible party or parties to accept their culpability and pay at least some of the funds upfront. There needs to be a way to estimate the likely cost, and a mechanism for additional payments if the initial payments do not meet the needs. This arrangement can be funded by more than one entity, so could combine industry funding with government funding, for example.

Option 2 – the administrator makes recommendations for payments

320. This is the model used by ombudsmen, including the Parliamentary and Health Service Ombudsman, which make recommendations to healthcare providers that they should pay compensation. Ombudsman recommendations can be binding (they must be paid) or non-binding (the healthcare provider has a choice over whether to pay or not).

321. Recommendations made by the Parliamentary and Health Service Ombudsman are non-binding but are almost always complied with. If recommendations are non-binding, there needs to be provision in place so claimants know that the recommended redress will be paid.

322. This option does not require upfront funding and can accommodate payments from multiple parties, with the share from each payer either determined by considering each individual case or by attributing liability on a pre-determined basis across all cases.

Option 3 – a government department as the administrator

323. If a scheme is entirely government funded, payments can be made by the relevant government department from its departmental budget. This allows the department to retain direct control of the funds until they are paid out but cannot easily accommodate payments from other entities or from industry.

Conclusion on how to hold funds

324. Using an ombudsman approach at least for the Interim Scheme would be our preferred choice as we believe it would be quicker and simpler to set up schemes where upfront funding is not required. The Commissioner recognises that the final decision rests with government.

Miscellaneous issues

Capacity

325. An issue that we encountered frequently in our discussion with valproate-affected families was that of mental capacity. This feature is also different to many of the existing redress schemes in operation in England, where lack of capacity of their beneficiaries is far less of an issue.

326. When setting up both the Interim Scheme and the Main Scheme, there needs to be careful consideration of how to address this issue. Families may already have arrangements in place through the appointment of a deputy or deputies, who operate under the supervision of the Court of Protection. Others have said to us that they would like their child to be supported by a professional deputy throughout the application process – and beyond (in terms of how to manage any financial awards).

327. The government will need to consider whether the costs relating to professional deputies and/or costs of engaging the Court of Protection in relation to financial matters will need to be met by the individual who lacks capacity, or the scheme itself. If the scheme is covering these costs, options could include individual provision of Court of Protection/deputyship costs or for the scheme itself (or a solicitors' firm with expertise in this area) to handle the Court of Protection/deputyship issues on a collective basis. Either way, adequate financial provision will need to be made available by the government to cover this additional administrative cost.

Support for those seeking redress

328. All stages of the application process (whether for the Interim Scheme or Main Scheme) need to be accessible and inclusive to patients, who should be able to navigate the process independently. This is in keeping with two of the key principles of redress we cited with approval at the start of chapter 4.

329. But we recognise that some patients would welcome access to independent support to help them prepare and submit their applications, particularly when it comes to individualised applications for the Main Scheme. Independent support has the potential to speed up the application process for patients but does not guarantee it.[164]

330. This type of application support could be provided in-house by caseworkers, by independent advocates, or by qualified legal representatives.

331. While the Commissioner expresses no preference on this issue, we did ask patients about their attitude to accessing compulsory support via a legal representative. If legal support was genuinely 'free' and did not affect the size of financial awards, there was strong support from patients that they should be required to access it (75.3%). However, this level of support falls to around 50% if the provision of compulsory legal support negatively affected the value of their financial awards.[165]

332. Regardless of the decision taken on legal support, any scheme must, at the very least, effectively signpost harmed patients to services which provide emotional support regardless of whether they qualify or even wish to apply for payment under the redress scheme. This could be counselling, therapy or support from a link worker as set out in chapter 4.

Recommendation 9

Both the Interim Scheme and the Main Scheme should effectively signpost harmed patients to services which can provide them with free emotional support.

Capitalised or periodic redress payments?

333. Redress paid via the Main Scheme could either be paid as a capitalised sum to cover both the harm to that point and all future harm. Alternatively, payments could be made on a periodic basis to cover harms as they occur.

334. The final decision will rest with the administrators of the Main Scheme, but we would expect that some elements, including any payments for past harms and non-economic elements, would be paid as a lump sum. Payments for ongoing harms or needs, for examples loss of income, could then be paid on a periodic basis, if this is what patients prefer. This allows for the level of payment to be adapted if required, as needs change.

Benefits and taxation

335. Lump sum litigation settlements for personal injury claims are free from tax and no capital gains is charged on the settlement (which includes any interest from the date of the injury to the date that the settlement is agreed upon). Periodic payments are treated as taxable income, either as annuities or as other payments.

336. Care needs to be taken when considering how payments from these schemes interact with taxation, social security and other benefits, such as educational support and social care assessments. There are a number of examples from infected blood and thalidomide which would be used going forward.[166]

337. One of Sir Robert Francis KC's key principles of redress, that we said should be incorporated in any redress scheme under Recommendation 1, was 'improving'. He defined this as:

> **"Improving. No claimant for compensation should be worse off than they would be without such a scheme, and an award of compensation should not prevent the pursuit of any entitlement to bring legal proceedings for the same subject matter."**[167]

338. We have heard directly from patients the importance of this point – 92.8% of respondents to our survey agreed or strongly agreed with the statement that 'financial awards made through the redress scheme should not affect my entitlement to social security benefits'.[168]

339. The Commissioner cannot overstate the importance of this point to government. She has not made a separate recommendation on this point because it is captured by her Recommendation 1 and the incorporation of the Francis principles into the redress scheme for pelvic mesh and valproate.

Litigation settlements

340. The First Do No Harm review stated that individuals who had got compensation from litigation or from out-of-court settlements would not need recourse to a redress scheme.[169] However, patients have varying views on this issue on what is clearly a sensitive area, and we would encourage government to explore these further before making a final decision.

341. In particular, government will need to consider the following.

- For those patients who have already received financial compensation through litigation or a settlement: a decision as to whether to prevent access to the Interim Scheme and/or Main Scheme. In our redress survey, 54% of respondents said that those who had already received compensation through other legal means should not be denied access to any redress scheme. 18% said that they should be denied access and 28% said they did not know or had no opinion.
- For all patients who receive financial compensation through litigation or an out-of-court settlement in the future: a decision as to whether to insert a 'claw-back' provision on payments from either the Interim Scheme or Main Scheme. This would require a person to repay all or some of the monies that they have received from the redress scheme if they subsequently receive financial compensation through litigation or a settlement.

Government recovery

342. Ordinarily, if an individual receives compensation from litigation for an injury, the government's Compensation Recovery Unit will be notified by the compensator and will recover the following costs from the claimant's awarded damages.

- Amounts of social security benefits paid because of the injury if a compensation payment has been made (the Compensation Recovery Scheme). As the benefits have already been paid to the claimant, this means the taxpayer is fairly compensated.
- Costs incurred by NHS Hospitals and Ambulance Trusts for treatment from injuries from road traffic accidents and personal injury claims (recovery of NHS charges). This is subject to an overall cap – currently set at £57,892 – and does not reflect the actual cost of NHS services provided.[170] If payment into the schemes is made by manufacturers, then consideration is needed of whether full recovery of NHS costs should be sought on a 'polluter pays' basis.[171]

343. The government will have to consider whether, given that the redress proposed is not the full compensation that a litigation settlement would be, the Compensation Recovery Unit should be notified of any financial redress offered.

344. Our recommendation is that, given the sums offered under both the Interim Scheme and Main Scheme will be ex gratia, the Compensation Recovery Unit is not involved.

345. If an out-of-court settlement funded by industry is administered as part of the redress, this issue would need additional consideration.

Sources of funding

346. There are three possible sources of funding for the redress scheme (encompassing both the non-financial and financial aspects): the government, industry, or a combination of the two. Clearly government has levers with regards to extracting funds from industry, but it would be a decision for them if and how to exercise them. The moves by government to extract funding from manufacturers associated with the Grenfell Tower tragedy may serve as a useful case study.[172]

347. Mesh patients, in particular, believe industry should contribute to a scheme and expressed being uncomfortable at the thought of funding for any financial redress scheme coming from NHS budgets.

348. The key question for government is whether it could reach agreement with industry so that the redress schemes administer an out-of-court settlement funded by industry alongside the government contribution. This option would require dialogue with both claimant lawyers and industry. If this option is available, oversight of the level of legal fees involved in the administration of any settlement is needed from the outset, similar to the judicial oversight of fees in class actions. Care must be taken to avoid a situation such as the Australian pelvic mesh settlements where legal and administrative costs made up around a third of the settlement figure.[173]

349. There may be greater scope to engage industry to provide support for elements of non-financial redress that we suggested in chapter 4 – for example, research and education workstream, where it could build on existing work. Such engagement is more likely to succeed if completed on a 'system-wide' basis, acknowledging the different expertise that each organisation can bring.

350. Negotiations with industry about potential contributions (whether financial or otherwise) must not delay the implementation of either scheme or detract from the responsibility of the healthcare system. Funding should be provided by government immediately. It would then be for the government to try to recoup funding from industry, should they wish to do so.

351. Irrespective of the source of funding, the overall level of funding provided must be sufficient. Funding for previous ex gratia support schemes have not always been so. For example, in 2015, the All-Party Parliamentary Group on Haemophilia and Contaminated Blood described the previous funding schemes for infected blood support in England as follows:

> **"Successive governments have only ever expanded support in a haphazard and reactive way. There has never been a comprehensive and holistic assessment of the precise level of payments and resources necessary to sufficiently provide for those affected. Consequently, we cannot presently be sure whether the current support individuals receive is sufficient for their needs, given the effects of their conditions."**[174]

352. This approach to funding ex gratia schemes must not be repeated.

Awareness raising

353. A redress scheme is only useful if people know about it. There is a clear need for a co-ordinated, inclusive and national communications campaign to support awareness raising around redress.[175] Such a campaign needs to learn the lessons from the Windrush Compensation Scheme and include the use of local radio, a public service broadcast and face-to-face events.[176] It should also make use of the NHS website.[177]

354. Setting up a community fund should also be considered. This would allow patient organisations to apply for funding to promote and share information about the redress scheme. A key feature of both these interventions, as the First Do No Harm review stated, is the fact that patients turned to each other for help and mutual support, and this fact should be used by the government.[178]

Recommendation 10

The government must ensure that the launch of the Interim Scheme and the Main Scheme is accompanied by an awareness raising campaign to ensure that all potentially eligible patients are made aware of it. The government needs to make specific efforts to ensure those patients from disadvantaged and marginalised groups are reached.

Chapter 6:

The numbers affected

> "You don't expect a 20-minute operation to change your life and your relationship so intensely."
>
> (Pelvic mesh harmed patient)

> "I want [their child] to have a meaningful life, a safe environment to live in, appropriate carers, meaningful activities."
>
> (Parent of valproate harmed patient)

Summary

- There remains significant uncertainty around the estimates of the valproate and pelvic mesh harmed population. We are also conscious that eligibility decisions by the government later down the line may then further change those eligible for any scheme.
- The award of an interim payment, as recommended in chapter 4, would be the best way to better define and quantify the harmed populations. The scope for adding further precision by government-commissioned research is limited.
- The lack of data is a direct result of the healthcare and regulatory failures for which the government is ultimately responsible. This should not be used as justification for delaying or not proceeding with the creation of a redress scheme.
- However, in terms of broad estimates of overall directly harmed populations:
  - for pelvic mesh – a reasonable starting point for the lower end of the range of the estimated harmed population in England is 10,000, with more work needed to produce the upper end of any estimate
  - for valproate – a reasonable range for the estimated harmed population in England appears to be between 10,000 to 17,000

355. There remains significant uncertainty around the estimates of numbers harmed by valproate and pelvic mesh and the range of harm.[179] Future policy decisions about eligibility criteria could then further limit who is deemed eligible.

356. The lack of basic information in this area means, unsurprisingly, that more detailed data such as equality related data also does not exist, despite the anecdotal evidence that we heard and evidence from France which suggests potential disparities in valproate harm, for example.[180]

357. Our overriding advice to ministers is for the government to award an interim payment under the Interim Scheme to help establish the harmed population both in terms of numbers and extent of harm. This in turn would allow for more robust estimates of costs for the proposed Main Scheme, as with Windrush Compensation Scheme and the infected blood scheme.[181]

358. While the Commissioner is sensitive to the government concerns about the need to avoid an unlimited spend, we do not believe the current lack of concrete numbers should be used to justify withholding redress payments.[182] The government should not use the failure of adequate data collection that was an error on the part of the regulatory system to deny the award of redress for those harmed.

Pelvic mesh

Number of pelvic mesh procedures

359. The First Do No Harm review stated:

> **"The system does not know, so neither do we, just how many women have been treated for stress urinary incontinence and the repair of pelvic organ prolapse using polypropylene mesh."**[183]

360. Overall, we believe that this statement remains accurate – and that it is a problem not unique to England. The number of patients implanted with pelvic mesh worldwide remains unknown. In 2022, a Scottish parliamentary briefing paper concluded that: "The number of women suffering complications [in Scotland] is not known, because there is currently no reliable information."[184]

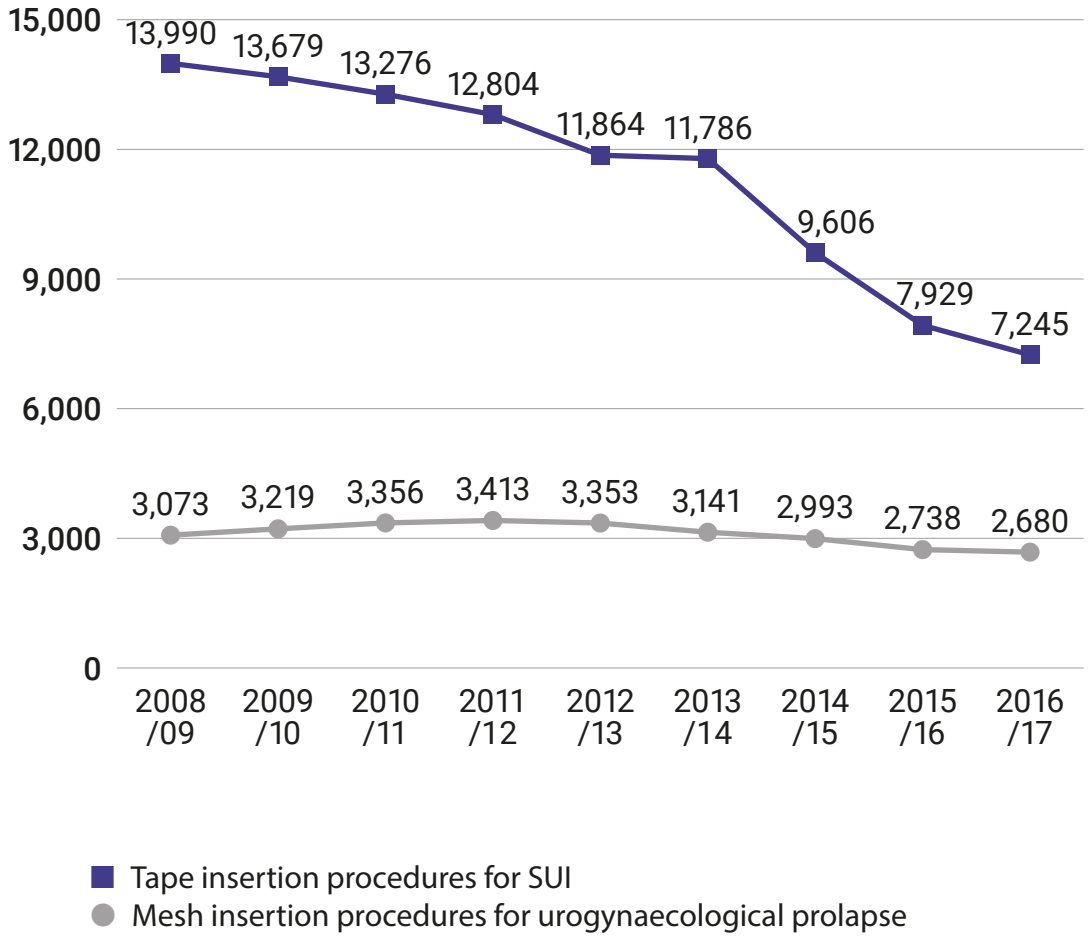
361. Polypropylene pelvic mesh sling was first available in the UK from 1998 and we have suggested a number of cut-off dates, with the latest being 2020.

362. For the period 2008 to 2017, the starting point in terms of analysis is the 2019 NHS Digital 'experimental' retrospective review of procedures completed in England.[185] This review stated that:

- between April 2008 to March 2017, 100,516 patients had a reported tape insertion procedure for SUI
- between April 2008 to March 2017, 27,016 patients had a reported mesh insertion procedure for urogynaecological prolapse

363. The yearly figures are shown below in figure 5.

Figure 5: Mesh insertion procedures in England



Source: Retrospective Review of Surgery for Urogynaecological Prolapse and Stress Urinary Incontinence using Tape or Mesh[186]

364. These figures total 127,532 procedures in England for SUI or urogynaecological prolapse between April 2008 and March 2017.

365. However, as the First Do No Harm review stated, we know that this data is incomplete.[187] It only covers procedures carried out in NHS hospitals, not private procedures.[188] A procedure can only be recorded in the Hospital Episode Statistics data once it is assigned a procedure code (known as a OPCS code), and the relevant procedures were only allocated their codes in 2006 to 2007. Even once a procedure is allocated an OPCS code, it takes time for a code to be used consistently.

366. Once private procedures are included, and the timeframe is expanded to include the period 1998 to 2020, we think that the number of pelvic mesh insertion procedures for SUI or POP in England could be more than 200,000.[189]

Range and severity of harm

367. Reported complication rates for pelvic mesh vary considerably. This is often because of how an 'adverse outcome' is defined by the study in question and who reports the presence or absence of this outcome – the patient or the clinician. For example, many of the academic studies focus on mesh removal rates as the definition of an adverse outcome. These issues led the First Do No Harm review to conclude that: "The current data does not reflect true complication rates."[190]

368. Unfortunately, as referenced in chapter 2, we have been informed that the expected main development since 2020 – NHS England's retrospective audit of pelvic floor surgery – has been delayed, with no indication of a publication date. When it is published, it may provide further evidence on rates of complication, particularly long-term complication rates.

369. Notwithstanding these limitations of the current research, we are aware that ministers would be interested in some estimations of complication rates as this will likely have some effect on the number of potential applicants to any redress scheme. These figures are illustrative only and are in no way designed to represent a comprehensive analysis of the literature. They also make no attempt to compare the effectiveness of mesh versus other surgical and non-surgical interventions for SUI or POP.

370. A NHS Digital 2018 study found that the "best working estimates" of cumulative removal rates (indicating the presence of complications) within the nine-year study period are 3.57% for tape for SUI and 1.32% for mesh for prolapse.[191]

371. Other academic studies put the broader two-year complication rate for women who received synthetic mesh either as part of their treatment for SUI or POP at 12%, of whom 9% required a surgical removal.[192]

These figures are similar to another research study where it was estimated that 9.8% of patients undergoing surgical mesh insertion for SUI experience a complication peri-procedurally within 30 days or within five years.[193] This study also added that this figure was "likely a lower estimate of the true incidence".[194]

372. Data derived from patient reported outcome measures is another source of evidence on complications. We are grateful to members of the APPRAISE team at Leeds Beckett University and their analysis of a multi-site dataset of the ePAQ pelvic floor (ePAQ-PF) questionnaire.[195]

373. The ePAQ-PF questionnaire is completed as part of routine care across many NHS urogynaecology sites in the UK to assess symptomatology, quality of life and the extent to which symptoms 'bother' the patient – although it is not completed specifically as a post-surgical outcome measure. However, it provides another reference point, this time based on patients' feedback on clinical outcomes.[196]

374. Out of this dataset, they were able to identify 416 patients who reported having mesh used in their treatment.[197] Of these 416 patients:

- 244 patients (59%) reported a possible mesh complication or adverse outcome[198]
- 21.5% (84) reported having had a mesh repair or revision surgery that was recorded as a treatment – other mesh patients may have had a mesh repair or revision but if they have not clearly stated this in their free-text answers, they will not have been included in this group

375. The APPRAISE team also provided additional analysis on the range and severity of mesh complications of the same 416 patients referenced above – via the four 'dimensions' of the ePAQ-PF, namely urinary, bowel, vaginal and sexual symptoms. Each dimension comprises a number of symptom 'domains' that use standardised multiple-choice questions to assess the frequency and impact of pelvic floor symptoms. The urinary, bowel and vaginal dimensions have an additional quality of life domain.

376. For the 416 mesh patients, it was observed that the symptom domains with the highest scores (indicating a worse quality of life) were overactive bladder, irritable bowel, vaginal pain and sensation, sex and urinary, sex and vagina, and the urinary, vaginal and sex quality of life domains. In addition, the 416 mesh patients had significantly worse ePAQ-PF scores on 18 of the 20 symptom and quality of life domains, when compared to the 'non-mesh' group.[199]

Overall: mesh

377. Given the large number of pelvic mesh procedures, we acknowledge relatively small differences to the complication rates have quite large impacts on the number of patients that could potentially be eligible to access a redress scheme. The number eligible will also depend on the nature of government decisions around final eligibility criteria as set out in chapters 4 and 5.

378. To try and provide some more certainty, we think that another useful reference point for overall numbers is the Scottish Mesh Fund.[200] This offered £1,000 to patients who were implanted with trans-vaginal mesh by the NHS in Scotland and who experienced complications because of their implant. Scottish Government officials told us that this fund received 650 applications before it closed on 30 June 2022. This number of applicants was in line with officials' assumptions from analysing the membership of the largest Scottish support group (understood to be around 700 at the time).

379. All other things being equal (and noting that the Scottish scheme did not include trans-abdominally inserted POP mesh), translating this Scottish figure onto England's population produces an estimated range of around 8,000 to 10,000 potential applicants (similar to the approximately 10,000 members that the Sling the Mesh support group have on Facebook).[201]

380. Assuming 200,000 mesh operations have been performed in England, this range of 8,000 to 10,000 would represent 4% to 5% of this population. This aligns with the lower end of the reported complication rates set out above.

381. Therefore, we think that a figure of 10,000 should form the lower end of the estimate of the number of patients harmed. We are unable to suggest an upper estimate. As set out in chapter 5, one option, to manage this uncertainty, would be for the government to announce funding for the initial 10,000 claims under the Interim Scheme, with a guarantee to provide more should more eligible patients come forward.

Valproate

Numbers exposed

382. There has been no official estimate of the number of children exposed to valproate in utero since it was licensed in 1973. Information has not been collected centrally, a position that has been confirmed by the government more recently.[202, 203]

383. One of the government's responses on this subject, when asked, is worth citing in full, as it neatly illustrates the problem faced:

> **"Limitations to historical data recording and collation mean that the total number of children diagnosed with congenital malformations or neurodevelopmental disorders following exposure to valproate in utero in England or across the United Kingdom since its authorisation is very difficult to estimate."**[204]

384. This response correctly notes that the limitation of historic data recording makes estimates very difficult. We do not have, nor are ever going to have, a complete picture of valproate prescribing since 1973, much less a complete picture of valproate prescribing during pregnancy. Even if we had, there would then be an additional question of seeking to verify adherence to prescribed treatment. There are always going to be knowledge gaps.

385. As the First Do No Harm review stated, there have been estimates from both campaign organisations and academics. From these sources, the First Do No Harm review stated that: "A reasonable estimate is approximately 20,000 people harmed in the UK)."[205] We think that it would be useful for policymakers to understand how these sorts of estimates are generated. Therefore, below we have explained the methodology most used by researchers to generate this 20,000 estimate and, importantly, modified it so that it covers our relevant period and is England only. The use of specific figures throughout this part of the chapter should not be interpreted as meaning we have generated any greater certainty in this space.

386. By way of background, of these estimates use research based on The Health Improvement Network (THIN). THIN is a database of anonymised patient data collected since 1994, at a sample of primary care clinics across the UK. The data is broadly representative of the UK population in terms of patient characteristics. It records the data collected during a patient's visit to their GP, including prescriptions and health data such as pregnancy. Any research using the THIN database is not based on actual prescribing rates for the whole of the UK – instead it is an estimation from the data held.

387. Data from THIN allowed researchers in 2012 to provide the percentage of pregnancies where anti-epileptic drugs were prescribed between 1994 and 2009 (inclusive).[206] For valproate, this percentage fluctuated across the years between just under 0.3% and less than 0.1%. Assuming that this is representative for the whole of the UK, these percentages (also known as the exposure rates) from the 2012 research paper – rounded to the nearest 0.05% – can be combined with Office for National Statistics data of annual live births in the UK for each of those years, to produce estimates for the numbers of babies exposed to valproate. This methodology produces an estimate of 14,426 exposed pregnancies across the UK for the years 1994 to 2009 (inclusive).

388. Additionally, we can use two other sources to extend our estimate to cover the period 1973 to 2017. This period covers the core dates of the Interim Scheme – as set in chapter 5 – but without prejudice to the decision by the government on the choice of a cut-off date.

389. For the period 1973 to 1993 (inclusive), we have assumed a consistent exposure rate of 0.15%, based on our understanding of the exposure rate assumed by the researchers who supported INFACT's evidence to the First Do No Harm on this issue. This 0.15% figure represents the average exposure rate across the later years of 1996 to 2009 found by the 2012 study, previously referenced. However, as those behind this figure acknowledged, it may be a slight over-estimation given that in the early years of this period, it is likely prescribing rates started lower as clinicians got used to the drug.

390. For the period 2010 to 2017, we have used a lower exposure rate of 0.08%, based on a MHRA study that covers this period.[207] This methodology assumes that the 0.08% figure would be consistent in each of these years, as well as across all four nations of the UK. Again, this figure of 0.08% can be combined with the annual live births for the UK between 2010 and 2017 (5,643,726) to produce a figure of 4,515 exposed pregnancies.

391. We acknowledge that of these three periods, the estimate for the period 1973 to 1993 is likely to be weakest. Ministers could commission further academic research, potentially supported or overseen by the MHRA on this period with the aim of generating a stronger evidence base to make a new calculation. The MHRA would need to agree that there were potential new sources of usage data available that have been unexamined before commissioning.

392. Even if the MHRA believes such data does exist, we remain strongly of the view that the best evidence will derive from the launch of the interim scheme.

393. It is worth noting that France has faced the same questions regarding numbers given that they launched a valproate-specific redress scheme, as discussed in chapter 2. A 2017 study from the Agence nationale de sécurité du médicament et des produits des santé – France's equivalent to the MHRA – estimated that between 2,150 and 4,100 children were affected by a severe congenital defect caused by exposure to valproate between 1967 and 2016.[208]

Prevalence, range and severity of harm[209]

394. We have been greatly assisted by Dr Rebecca Bromley, and her team at the University of Manchester, in understanding the range and severity of valproate harm in greater detail.

395. The headline figures in terms of those harmed by valproate exposure in the womb has not changed from the position in the First Do No Harm review in 2020.210 In its 2022 drug review, the MHRA confirmed that: "Exposure of an unborn child to valproate in utero is associated with a high risk of congenital malformations (11%) and neurodevelopmental disorders (30 to 40%), which may lead to permanent disability."[211]

396. With regards to congenital malformations, risks are higher for spinal, skeletal, cardiac and facial malformations.[212] However, even if the organs have formed typically (without congenital malformation), there can be functional difficulties and associated health problems. For example, although the ears of a person with FVSD may be 'normal' in terms of organ structure, the person may experience hearing issues – with similar situations for visual problems and digestive issues (among others). Finally, joint laxity is also very common and limits physical functioning and causes fatigue. The list of physical health conditions can often be long and complex.

397. Adverse neurodevelopmental outcomes encompass cognitive, sensory, emotional and behavioural functioning difficulties.[213] These include delayed development, lower IQ, poorer memory, poorer language and adaptive behaviour, and higher rates of neurodevelopmental disorders, such as Autism Spectrum Disorder and Attention Deficit Hyperactivity Disorder.[214] As discussed in chapter 3, these conditions often then create mental health challenges such as anxiety and depression.

398. Harm is generally dose-dependent, with those exposed to higher doses in utero generally presenting with the most significant neurodevelopmental and congenital symptoms.[215] However, clinicians were keen to point out that the focus in the research to date on high dose-exposed children should not obscure their observations of harm among low dose-exposed children.

399. Those with a formal FVSD (who are likely to have been exposed to higher doses) generally present with the most severe symptoms, with a recent study finding that, among a group with such a diagnosis:

- 14.4% experienced severe everyday cognitive difficulties
- 43.3% experienced moderate everyday cognitive difficulties
- the prevalence of Autism Spectrum Disorder was extremely high (62.9%) versus the 1.1% background rate among the general population in the UK[216]

400. However, as we discuss in chapter 4, we have heard from patients and clinicians that receiving a diagnosis of FVSD is often hard, and parents may receive an alternative diagnosis such as autism, or perhaps no formal diagnosis at all.

401. Lastly, clinicians who work with those exposed to valproate in utero reported to us that they are increasingly seeing young adults 'grow into' their defects. They explained how often children and adolescents with FVSD may be able to cope when they are in the structured environment of an educational setting. However, their inability to develop more complex social and cognitive skills means that they cannot lead independent adult lives. As a result, diagnosis is often late.

Overall: valproate

402. Taking the upper estimate of complication rates (40%) and combining it with the estimated 33,489 people affected by in utero exposure to valproate in England produces a central estimate is terms of harmed population of around 14,000, and a range of 10,000 to 17,000, as illustrated by the table on the following page.

Time periods (inclusive)	Estimated number of people exposed to valproate in utero
1973 to 1993	20,458
1994 to 2009	14,426
2010 to 2017	4,515
Total (UK-wide)	39,399
Less 15% (to generate an England-only figure – as England comprises around 85% of the UK population)	33,489

Explanation	Estimated number of people harmed by in utero exposure to valproate
Assuming 40% of those exposed are harmed*	13,396
An estimated range (the central estimate set out above, plus or minus 25%, given uncertainties)	10,047 to 16,745

* This calculation assumes that around 10% of those with congenital malformations will be a subset of the larger percentage with neurodevelopmental disorders – not in addition to. We understand this is likely to be the case, but the government may want to investigate this point further with clinicians.

Conclusion

1. This report has sought to provide a robust and comprehensive overview of the options for redress for those harmed by valproate and mesh. We have focused on the 'how' – but made clear our views on the 'why' in chapter 1. The case for redress is clear. While redress, financial or otherwise, will not turn back the clock nor change the past, it can provide support to allow those harmed to move forward in their lives.

2. As set out in the introduction, there is a compelling and urgent need for an approach rooted in the principles of restorative practice. The needs of those who were harmed, and their loved ones, must be central to any redress scheme. It is only by co-producing with patients that the government can ensure these needs are understood and met.

3. It is important to acknowledge the work which has occurred since the publication of Baroness Cumberlege's First Do No Harm review. The system has responded with many positive initiatives and workstreams, but they can be disjointed, are often not evaluated and generally do not go far enough. For example, there remains inadequate diagnosis of FVSD and inadequate support for those who are diagnosed. And, while NHS England's Outcomes and Registries Programme is underway, there is still much work to be done. The Commissioner will continue to welcome all progress in this space, but what has been done so far falls far short of providing redress to those harmed.

4. Patients were generous with the team in providing time to discuss their experiences and respond to our survey. What happened to these patients was not simply a failure of regulation – it was a turning point in their lives. In many of these cases, it has torn apart families, generated significant economic hardships and left young adults with a lifetime of uncertainty ahead of them.

5. Redress must span financial and non-financial aspects to make the lives of those harmed better. On non-financial redress, there needs to be work across government to provide the holistic and wraparound support that is required in addition to any financial redress offered for redress to be restorative. Currently, too many of those harmed have poor experiences when accessing the very public services designed to support them.

6. For financial redress, this report highlights that the inadequate data collection means that the numbers of those harmed is complex to understand. However, this must not be used as an excuse for inaction. The fact that we struggle to know how many people were affected further underscores the failure of regulation that supports the case for redress.

7. As this report sets out, an interim payment will facilitate the government to identify the size of the harmed population. It will provide some redress to those who need it rapidly and it will begin the restorative process. This payment should be followed by a bespoke Main Scheme which seeks to understand the personal impact the harm has caused. For the design of this bespoke scheme, we have highlighted numerous examples which the government can draw from in this report, which will need to be discussed with patients to understand what is most suitable.

8. To conclude, the government now has a responsibility not to disappoint the hopes of those harmed which they have raised by commissioning this report. By implementing a redress scheme built on the principles of restorative practice, the government can begin the process of putting right what has gone wrong.

Annex A: References

(All links last accessed in November 2023)

Endnotes

1 *First Do No Harm – The Report of the Independent Medicines and Medical Devices Safety Review* (2020). Available at: **https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf**

2 *First Do No Harm – The Report of the Independent Medicines and Medical Devices Safety Review* (2020). Available at: **https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf**

3 This point was outside the scope of the terms of reference of First Do No Harm: *First Do No Harm – The Report of the Independent Medicines and Medical Devices Safety Review*, page 27 (2020). Available at: **https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf**

4 To maintain the confidentiality of the patients' views that we cite, we have modified some of the quotes to remove possibly identifying information. All changes to direct quotes are marked with square brackets.

5 For a discussion of the importance of financial and non-financial support, see: Davies, J. M., Steinke, C. and Flemons, W. W., *Fatal Solution: How a Healthcare System Used Tragedy to Transform Itself and Redefine Just Culture,* Routledge (2022).

6 Wailling, J., Marshall, C., and Wilkinson, J. *Hearing and responding to the stories of survivors of surgical mesh: Ngā kōrero a ngā mōrehu – he urupare (A report for the Ministry of Health)*. Wellington: The Diana Unwin Chair in Restorative Justice, Victoria University of Wellington, page 35 (2019). Available at: **https://www.health.govt.nz/publication/hearing-and-responding-stories-survivors-surgical-mesh**; The National Collaborative for Restorative Initiatives in Health. *He Maungarongo ki Ngā Iwi: Envisioning a Restorative Health System in Aotearoa New Zealand*. Wellington, Aotearoa NZ (2023). Available at: **https://www.hqsc.govt.nz/resources/resource-library/he-maungarongo-ki-nga-iwi-envisioning-a-restorative-health-system-in-aotearoa-new-zealand/**

7 Wailling, J., Marshall, C., and Wilkinson, J. *Hearing and responding to the stories of survivors of surgical mesh: Ngā kōrero a ngā mōrehu – he urupare (A report for the Ministry of Health)*. Wellington: The Diana Unwin Chair in Restorative Justice, Victoria University of Wellington, page 35 (2019). Available at: **https://www.health.govt.nz/publication/hearing-and-responding-stories-survivors-surgical-mesh** – citing Moore, C. *The mediation process: Practical strategies for resolving conflict*. New York, US. Wiley and Sons (2014).

8 **https://www.merseycare.nhs.uk/restorative-just-learning-culture**

9 Wailling, J., Marshall, C., and Wilkinson, J. *Hearing and responding to the stories of survivors of surgical mesh: Ngā kōrero a ngā mōrehu – he urupare (A report for the Ministry of Health)*. Wellington: The Diana Unwin Chair in Restorative Justice, Victoria University of Wellington, page 35 (2019). Available at: **https://www.health.govt.nz/publication/hearing-and-responding-stories-survivors-surgical-mesh**

10 *First Do No Harm – The Report of the Independent Medicines and Medical Devices Safety Review*, paragraph 2.3 (2020). Available at: **https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf** We also acknowledge that the children born to mothers who took valproate in pregnancy will be male and female.

11 Francis QC, R. *Compensation and Redress for the Victims of Infected Blood – Recommendations for a Framework* (2022). Available at: **https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1081007/Compensation_and_Redress_for_the_Victims_of_Infected_Blood_-_Recommendations_for_a_Framework_-_Sir_Robert_Francis__Final_.pdf**

12 Aneurin Bevan MP, Minister for Health: 1945 to 1951.

13 Rt Hon Jeremy Hunt MP. *Debate on Medicines and Medical Devices Safety Review* (2018). Available at: **https://hansard.parliament.uk/commons/2018-02-21/debates/7DA2E2F3-E1E6-40CB-8061-680E0399CA97/MedicinesAndMedicalDevicesSafetyReview**. The three cases being valproate, pelvic mesh and hormone pregnancy tests (that were not included in our terms of reference but were within those of the First Do No Harm review).

14 *Matt Hancock apologises on behalf of government over vaginal mesh implants* (2020). Available at*:* **https://www.youtube.com/watch?v=idm72E5zk3A**

15 Only 3% of our survey respondents said that the government had provided them with an adequate apology to date – see annex E (question 18).

16 Medicines and Medical Devices Act 2021. Available at: **https://www.legislation.gov.uk/ukpga/2021/3/enacted**

17 *Debate on Foetal Valproate Spectrum Disorder: Fatalities* (2022). Available at: **https://hansard.parliament.uk/commons/2022-12-07/debates/B2D90D97-EB69-4003-A813-A478491CA0A8/FoetalValproateSpectrumDisorderFatalities**

18 *Health and Social Care Committee oral evidence: IMMDS Review: follow up one-off session, HC 689* (2022). Available at: **https://committees.parliament.uk/oralevidence/12430/html/**

19 Our terms of reference are set out in annex C.

20 *Medicines and Medical Devices Act 2021,* section 1(1). Available at: **https://www.legislation.gov.uk/ukpga/2021/3/enacted**

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78 We note that several of these – including waiting times and uncertainties around transfers of responsibilities between healthcare professionals – are also mentioned in the recent MHRA Public Assessment Report, which referenced their work to understand more about 25 valproate-exposed pregnancies through contacting the prescribing GP/MHRA, *Valproate: review of safety data and expert advice on management of risks. Public Assessment Report*, paragraph 10.5 (2023). Available at: **https://assets.publishing.service.gov.uk/media/65660310312f400013e5d508/Valproate-report-review-and-expert-advice.pdf**

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102 Khanom S., Astill D., Astill N., Cozens J., Mann B., Garratt J., Bromley R., *The lived experience of young adults with Fetal Valproate Spectrum Disorder, and the perspective of their parents: A qualitative study.* (2023 – in preparation to be published).

103 Khanom S., Astill D., Astill N., Cozens J., Mann B., Garratt J., Bromley R., *The lived experience of young adults with Fetal Valproate Spectrum Disorder, and the perspective of their parents: A qualitative study.* (2023 – in preparation to be published).

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105 *The importance of human rights in our approach* (2023). Accessible at: **https://www.cqc.org.uk/assessment/importance-human-rights-our-approach**

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121 Department for Work and Pensions, Transforming Support: The Health and Disability White Paper, paragraph 15 (2023). Available at: **https://www.gov.uk/government/publications/transforming-support-the-health-and-disability-white-paper/transforming-support-the-health-and-disability-white-paper**

122 Department for Work and Pensions, Transforming Support: The Health and Disability White Paper, paragraph 15 (2023). Available at: **https://www.gov.uk/government/publications/transforming-support-the-health-and-disability-white-paper/transforming-support-the-health-and-disability-white-paper**

123 Khanom S., Astill D., Astill N., Cozens J., Mann B., Garratt J., Bromley R., *The lived experience of young adults with Fetal Valproate Spectrum Disorder, and the perspective of their parents: A qualitative study* (2023 – in preparation to be published).

124 HM Government, *Special Educational Needs and Disabilities (SEND) and Alternative Provision (AP) Improvement Plan.* (2023). Available at: **https://www.gov.uk/government/publications/send-and-alternative-provision-improvement-plan**

125 The 4 R's of Apology, Anne Bachle Fifer. Available at: **https://abfifer.com/blog/2023/03/the-4-rs-of-apology/**

126 See, for example, Apologies (Scotland) Act 2016. Available at: **https://www.legislation.gov.uk/asp/2016/5#:~:text=In%20this%20Act%20an%20apology,outcome%20with%20a%20view%20to**

127 The award of financial redress as part of an apology also emerged in New Zealand. See: Wailling, J., Marshall, C., and Wilkinson, J., *Hearing and responding to the stories of survivors of surgical mesh: Ngā kōrero a ngā mōrehu – he urupare (A report for the Ministry of Health)*. Wellington: The Diana Unwin Chair in Restorative Justice, Victoria University of Wellington, page 35 (2019). Available at: **https://www.health.govt.nz/publication/hearing-and-responding-stories-survivors-surgical-mesh**

128 Vincent C., Phillips A., and Young M., *Why do people sue doctors? A study of patients and relatives taking legal action*. The Lancet, vol. 343, pages 1609 to 1613 (1994). Available at: **https://doi.org/10.1016/S0140-6736(94)93062-7**

129 We note, for example, that the European Medicines Agency endorsed new measures on the use of topiramate, including the launch of a Pregnancy Prevention Programme. Available at: **https://www.ema.europa.eu/en/medicines/human/referrals/topiramate#:~:text=Topiramate%20must%20be%20discontinued%20if,weeks%20after%20stopping%20topiramate%20treatment**

130 *The Epilepsy Society launches 'Safe Mum, Safe Baby' campaign* (2021). Available at: **https://epilepsysociety.org.uk/latest/news/epilepsy-society-launches-safe-mum-safe-baby-campaign**

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132 See also Eriksson S. H., Tittensor P. and Sisodiya S. M., *National compliance with UK wide guidelines for usage of valproate in women of childbearing potential*. Seizure: European Journal of Epilepsy (2022). Available at: **https://doi.org/10.1016/j.seizure.2022.03.020**

133 *Scotland's Redress Scheme – How it Works.* Available at: **https://www.mygov.scot/apply-for-scotlands-redress-scheme/how-it-works**

134 *Infected Blood Inquiry, Interim Payments*. Available at: **https://www.infectedbloodinquiry.org.uk/psychological-support-provided-inquiry/interim-payments**

135 *First Do No Harm – The Report of the Independent Medicines and Medical Devices Safety Review*, paragraphs 5.16 and Appendix 7 (2020). Available at: **https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf**

136 MHRA, *Valproate: review of safety data and expert advice on management of risks. Public Assessment Report*, paragraph 18.1 (2023). Available at: **https://assets.publishing.service.gov.uk/media/65660310312f400013e5d508/Valproate-report-review-and-expert-advice.pdf**; *Safety of valproate – new study on risks in children of men taking valproate* (2023). Available at: **https://www.gov.uk/government/news/safety-of-valproate-new-study-on-risks-in-children-of-men-taking-valproate**; Martin M., Hill C., Bewley S., MacLennan A. H., Braillon A., *Transgenerational adverse effects of valproate? A patient report from 90 affected families*, Birth Defects Research, vol. 114, pages 13 to 16 (2022). Available at: **https://onlinelibrary.wiley.com/doi/epdf/10.1002/bdr2.1967**

137 See First Do No Harm: *First Do No Harm – The Report of the Independent Medicines and Medical Devices Safety Review*, page 138 (2020). Available at: **https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf** Their definition matches the NHS definition: *Pelvic organ prolapse – NHS.* Available at: **https://www.nhs.uk/conditions/pelvic-organ-prolapse/**

138 See also First Do No Harm: *First Do No Harm – The Report of the Independent Medicines and Medical Devices Safety Review*, paragraph 1.8. (2020). Available at: **https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf**

139 Francis QC, R. *Compensation and Redress for the Victims of Infected Blood – Recommendations for a Framework,* page 71 (2022). Available at: **https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1081007/Compensation_and_Redress_for_the_Victims_of_Infected_Blood_-_Recommendations_for_a_Framework_-_Sir_Robert_Francis__Final_.pdf**

140 Our patient engagement survey presented mixed results on this issue – see responses to statements (1) and (3) as part of question 23 in annex E survey results.

141 Mesh for the treatment of SUI is not inserted trans-abdominally.

142 *NICE IPG599 Transvaginal mesh repair of anterior or posterior vaginal wall prolapse* (2017). Available at: **https://www.nice.org.uk/guidance/ipg599**

143 *Government announces strict rules for the use of vaginal mesh*. Available at: **https://www.gov.uk/government/news/government-announces-strict-rules-for-the-use-of-vaginal-mesh** Trans-vaginally inserted mesh for SUI covers the common mesh procedures known as TVT and TVT-O.

144 The report itself was published on 22 July 2020.

145 The Pregnancy Prevention Programme was launched on 23 March 2018. *GOV.UK Guidance, Valproate use by women and girls*. Available at: **https://www.gov.uk/guidance/valproate-use-by-women-and-girls**

146 *Valproate Pregnancy Prevention Programme: actions required now from GPs, specialists, and dispensers* (2018). Available at: **https://www.gov.uk/drug-safety-update/valproate-pregnancy-prevention-programme-actions-required-now-from-gps-specialists-and-dispensers**

147 As discussed in paragraphs 281 and 282.

148 We discuss spectrum of harm in more detail in chapter 6.

149 *Injuries following in utero exposure to sodium valproate, A guide to ACC cover* (2022). Available at: **https://www.acc.co.nz/assets/provider/injuries-in-utero-exposure-sodium-valproate-acc8203.pdf**

150 Example templates of authority that NHS Resolution use are here, by way of examples: *Vaginal Mesh Form of Authority Hospital*. Available at: **https://resolution.nhs.uk/wp-content/uploads/2022/06/Form-of-Authority-Vaginal-Mesh-Hospital.pdf**; *Vaginal Mesh Form of Authority General Practice.* Available at: **https://resolution.nhs.uk/wp-content/uploads/2022/06/Form-of-Authority-Vaginal-Mesh-General-Practice.pdf**

151 Access to Health Records Act 1990, section 5(1)(b). Available at: **https://www.legislation.gov.uk/ukpga/1990/23/section/5#:~:text=(b)information%20obtained%20as%20a,would%20not%20be%20so%20disclosed**

152 *Redress Support Service, How We Help*. Available at: **https://www.redress-support.scot/how-we-help/**

153 *BBC News Infected Blood Inquiry: Charity chairman admits 'disgraceful' comments* (2021). Available at: **https://www.bbc.co.uk/news/uk-wales-56183342**

154 The Scottish Mesh Fund was open for 23 months (June 2020 to May 2022) – and this period was significantly interrupted by COVID-19.

155 This principle of compensation is sometimes referred to by the Latin phrase *restitutio ad integrum*. See *Livingstone v Rawyards Coal Co* (1880) 5 App Cas 25: "That sum of money which will put the party who has been injured in the same position as he would have been if he had not sustained the wrong for which he is now getting his compensation or reparation."

156 The Law Reform (Personal Injuries) Act 1948. Available at: **https://www.legislation.gov.uk/ukpga/Geo6/11-12/41/contents**

157 Redress for Survivors (Historical Child Abuse in Care) (Scotland) Act 2021. Available at: **https://www.legislation.gov.uk/asp/2021/15/section/36**

158 *Compensation Scheme failures have compounded injustices faced by Windrush generation – Committee finds* (2021). Available at: **https://committees.parliament.uk/committee/83/home-affairs-committee/news/159118/compensation-scheme-failures-have-compounded-injustices-faced-by-windrush-generation-committee-finds/#:~:text=The%20Committee%20urges%20immediate%20action,have%20acknowledged%20were%20wrongly%20subject**; Parliamentary and Health Service Ombudsman, *Windrush applicant waited over a year to be rejected*. Available at: **https://www.ombudsman.org.uk/making-complaint/what-we-can-and-cant-help/how-we-have-helped-others/windrush-applicant-waited-over-year-be-rejected**

159 The National Health Service Litigation Authority (Establishment and Constitution) Order 1995 (as amended). Available at: **https://www.legislation.gov.uk/uksi/1995/2800/made**

160 *England Infected Blood Support Scheme NHSBSA.* Available at: **https://www.nhsbsa.nhs.uk/england-infected-blood-support-scheme**; *Vaccine Damage Payment Scheme (VDPS) NHSBSA.* Available at: **https://www.nhsbsa.nhs.uk/vaccine-damage-payment-scheme-vdps**

161 *Covid vaccine injury victims 'betrayed' as claims plagued with delays, The Telegraph* (2023). Available at: **https://www.telegraph.co.uk/news/2023/04/17/covid-vaccine-damage-payment-scheme-claims-delays/**

162 Francis QC, R. *Compensation and Redress for the Victims of Infected Blood – Recommendations for a Framework*, page 130 (2022). Available at: **https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1081007/Compensation_and_Redress_for_the_Victims_of_Infected_Blood_-_Recommendations_for_a_Framework_-_Sir_Robert_Francis__Final_.pdf**

163 *MPs back amendment to speed up compensation for infected blood survivors and families*, The Hepatitis C Trust (2023). Available at: **https://www.hepctrust.org.uk/blog/2023/12/mps-back-amendment-to-speed-up-compensation-for-infected-blood-survivors-and-families/#:~:text=The%20new%20amendment%2C%20called%20New,of%20the%20infected%20blood%20scandal**

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166 The Social Security (Infected Blood and Thalidomide) Regulations 2017. Available at: **https://www.legislation.gov.uk/uksi/2017/870/made**

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168 See annex E (question 23).

169 *First Do No Harm – The Report of the Independent Medicines and Medical Devices Safety Review*, paragraph 1.39 (2020). Available at: **https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf**

170 *Recovery of NHS charges: tariff and cap increase from 1 April 2023* – GOV.UK (2023). Available at: **https://www.gov.uk/government/publications/compensation-recovery-unit-bulletins/recovery-of-nhs-charges-tariff-and-cap-increase-from-1-april-2023**

171 In environmental law, the polluter pays principle means that, where possible, the costs of pollution should be borne by those causing it, rather than the person who suffers the effects of the resulting environmental damage, or the wider community.

172 '*Severe consequences' for cladding companies who refuse to remediate, government warns investors* – GOV.UK (2023). Available at: **https://www.gov.uk/government/news/severe-consequences-for-cladding-companies-who-refuse-to-remediate-government-warns-investors#:~:text=To%20date%2C%20the%20three%20construction,t-heir%20products%20have%20made%20unsafe**

173 Longbottom J., *Pelvic mesh victims left unsure of futures as legal fees threaten to slash class action payout*, Australian Broadcasting Corporation (2022). Available at: **https://www.abc.net.au/news/2022-12-04/mesh-implant-class-action-shine-lawyers-payout-dispute/101728850**

174 The All-Party Parliamentary Group on Haemophilia and Contaminated Blood, *Inquiry into the current support for those affected by the contaminated blood scandal in the UK* (2015). Available at: **https://haemophilia.org.uk/wp-content/uploads/2017/02/appg_hcb_fr.pdf.pdf**

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176 *House of Commons Home Affairs Committee, The Windrush Compensation Scheme.* Available at: **https://committees.parliament.uk/publications/7936/documents/82209/default/**

177 The vCJD compensation scheme is referenced on the relevant page on the NHS website, for example: **https://www.nhs.uk/conditions/creutzfeldt-jakob-disease-cjd/**

178 *First Do No Harm – The Report of the Independent Medicines and Medical Devices Safety Review*, page 2 (2020). Available at: **https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf**

179 The First Do No Harm review reported that: "The system does not know, so neither do we, just how many women have been treated for stress urinary incontinence and the repair of pelvic organ prolapse using polypropylene mesh." *First Do No Harm – The Report of the Independent Medicines and Medical Devices Safety Review*, page 5 (2020). Available at: **https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf**

180 A 2017 French study reported that women exposed to valproate in pregnancy were more likely to be in receipt of *CMU complémentaire* – a form of social security that indicates a lower socio-economic status: *Report on the exposure of valproate and other medications for the treatment of epilepsy and bipolar disorder on the utero and the risk of major congenital malformations* (2017). Available at: **https://apesac.org/images/document/etudes/Valproate_Rapport_ANSM-CNAMTS_-juillet2017.pdf**

181 The Windrush Compensation Scheme was launched on 3 April 2019, but the associated primary legislation (the Windrush Compensation Scheme (Expenditure) Act 2020) did not receive Royal Assent until 8 June 2020. More recent work with regards to infected blood had the benefit of data from the existing entities, set up by the government between 1988 and 2011.

182 We also note that a similar situation in terms of lack of certainty over numbers was seen with the Windrush Compensation Scheme, but this was not considered a barrier to implementing the scheme. The impact assessment estimated the compensation spend to be between £21 million and £301 million depending on the number of eligible claimants who came forward. See: *Impact assessment: Windrush compensation policy* (2020). Available at: **https://assets.publishing.service.gov.uk/media/5e3c4245e5274a08e1d0929d/Windrush_compensation_policy_Impact_Assessment.pdf**

183 *First Do No Harm – The Report of the Independent Medicines and Medical Devices Safety Review*, page 5 (2020). Available at: **https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf**

184 Scottish Parliament Briefing (SPICe) paper, *Surgical mesh complications* (2022). Available at: **https://spice-spotlight.scot/2022/06/30/surgical-mesh-complications/**

185 NHS Digital, *Retrospective Review of Surgery for Urogynaecological Prolapse and Stress Urinary Incontinence using Tape or Mesh: Hospital Episode Statistics (HES), Experimental Statistics, April 2008 – March 2017* (2018). Available at: **https://digital.nhs.uk/data-and-information/publications/statistical/mesh/apr08-mar17/retrospective-review-of-surgery-for-vaginal-prolapse-and-stress-urinary-incontinence-using-tape-or-mesh-copy** This audit is 'experimental' because Hospital Episode Statistics data is designed to record how many treatments took place, not how many patients were treated. This is the first time any data set has been analysed using a pseudo-anonymised patient identifier to try to determine how many people were treated: *First Do No Harm – The Report of the Independent Medicines and Medical Devices Safety Review*, page 154 (2020). Available at: **https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf**

186 *Retrospective Review of Surgery for Urogynaecological Prolapse and Stress Urinary Incontinence using Tape or Mesh* (2018). Available at: **https://files.digital.nhs.uk/D2/99117D/Retrospective_Review_of_Surgery...-_exe.pdf**

187 *First Do No Harm – The Report of the Independent Medicines and Medical Devices Safety Review*, page 154 (2020). Available at: **https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf**

188 Mamza J.B., Geary R.S., El-Hamamsy D. et al, *Geographical variation in rates of surgical treatment for female stress urinary incontinence in England: a national cohort study. BMJ Open* (2019). Available at: **http://dx.doi.org/10.1136/bmjopen-2019-029878**

189 Gornall, J., *The trial that launched millions of mesh implant procedures: did money compromise the outcome?* BMJ, 363: k4155 (2018). Available at: **https://doi.org/10.1136/bmj.k4155**

190 *First Do No Harm – The Report of the Independent Medicines and Medical Devices Safety Review*, page 177 (2020). Available at: **https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf**

191 Letter to Professor Dame Sally Davies from Professor Steve Powis and Professor Keith Willett dated 14 May 2018, included as evidence submitted to the First Do No Harm Review: *The Independent Medicines and Medical Devices Safety Review Written Evidence Patient Groups: Pelvic Mesh,* pages 249 to 251 (2018). Available at: **https://www.immdsreview.org.uk/downloads/Evidence/FOR%20PUBLICATION%20Patient%20Groups%20-%20Pelvic%20Mesh.pdf**

192 Mesh, graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicentre, randomised, controlled trials (PROSPECT).

193 Keltie, K., Elneil, S., Monga, A. et al. *Complications following vaginal mesh procedures for stress urinary incontinence: an 8 year study of 92,246 women*. Sci Rep (2017). Available at: **https://doi.org/10.1038/s41598-017-11821-w**

194 Keltie, K., Elneil, S., Monga, A. et al. *Complications following vaginal mesh procedures for stress urinary incontinence: an 8 year study of 92,246 women*. Sci Rep (2017). Available at: **https://doi.org/10.1038/s41598-017-11821-w**

195 This multi-site ePAQ dataset of 7,198 patients includes patients who are attending for any urogynaecological problem (pre and post any intervention), not just mesh complications. Patients are not, therefore, responding to a call to specifically discuss adverse outcomes associated with mesh surgery. The specific dataset used for the analysis referenced in this report was composed of 5,717 patients.

196 Anyone who completes the ePAQ-PF has been referred to the urogynaecological clinic for investigation either by their GP or they could be follow-up patients, so it cannot be seen as representative of all patients who underwent mesh surgery.

197 Specifically, 416 is the total number of mesh patients in the ePAQ-PF dataset (who had self-reported having mesh which was coded as either a 'condition' (meaning that treatment was required for a mesh related complication or adverse outcome) or a 'treatment' (meaning that mesh was used to treat a condition such as prolapse or incontinence).

198 This figure relates to patients who have self-reported a mesh complication or adverse outcome. It could include those waiting for a mesh repair or revision, as well as those who may not have had any treatment to rectify the issue.

199 The two exceptions were the stress urinary incontinence domain (urinary dimension), and the evacuation domain (bowel dimension).

200 *About the original Scottish Government Mesh Fund that closed on 30th June 2022*. (2022). Available at: **https://www.nss.nhs.scot/patient-support-schemes/mesh-scheme/about-the-original-scottish-government-mesh-fund-that-closed-on-30th-june-2022/**

201 Sling the Mesh is the largest patient group covering both vaginal and rectal mesh.

202 *First Do No Harm – The Report of the Independent Medicines and Medical Devices Safety Review,* Annex F, page 10 (2020). Available at: **https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf** – citing a response to a Parliamentary Question tabled by Norman Lamb MP on 9 March 2018: *Norman Lamb MP, UK Parliament Written questions and answers Pregnancy: Sodium Valproate.* Available at: **https://questions-statements.parliament.uk/written-questions/detail/2018-03-09/131831**

203 See also, more recently: Alan Brown MP, *UK Parliament Written questions and answers Pregnancy: Sodium Valproate* (2023). Available at: **https://questions-statements.parliament.uk/written-questions/detail/2023-04-27/183124** and **https://questions-statements.parliament.uk/written-questions/detail/2023-05-09/184116**

204 *Alan Brown MP, UK Parliament Written questions and answers Pregnancy: Sodium Valproate* (2023). Available at: **https://questions-statements.parliament.uk/written-questions/detail/2023-05-09/184116**

205 *First Do No Harm – The Report of the Independent Medicines and Medical Devices Safety Review*, page 104 (2020). Available at: **https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf**

206 Man S-L., Petersen I., Thompson M., Nazareth I., *Antiepileptic Drugs during Pregnancy in Primary Care: A UK Population Based Study.* tit, vol. 7 (2012). Available at: **https://doi.org/10.1371/journal.pone.0052339**

207 *CPRD study monitoring the use of valproate in girls and women in the UK: January 2010 to December 2019* (2020). Available at: **https://assets.publishing.service.gov.uk/media/5ea000a1e90e07049a97d6ad/CPRD_valproate_usage_report_DSU_Feb_2020_final.pdf**

208 *France info, Depakine (valproate) has caused between 2150 and 4100 cases of malformations in infants since 1967* (2017) Available at: **https://www.francetvinfo.fr/sante/grossesse/depakine/la-depakine-a-provoque-en-france-entre-2150-et-4100-cas-de-malformations-majeures-chez-les-nourrissons-depuis-1967-annonce-l-agence-francaise-du-medicament_2154329.html**

209 See further MHRA, *Valproate: review of safety data and expert advice on management of risks. Public Assessment Report*, chapter 5 (2023). Available at: **https://assets.publishing.service.gov.uk/media/65660310312f400013e5d508/Valproate-report-review-and-expert-advice.pdf**

210 *First Do No Harm – The Report of the Independent Medicines and Medical Devices Safety Review*, page 104 (2020). Available at: **https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf**

211 *Valproate: reminder of current Pregnancy Prevention Programme requirements; information on new safety measures to be introduced in the coming months* (2022). Available at: **https://www.gov.uk/drug-safety-update/valproate-reminder-of-current-pregnancy-prevention-programme-requirements-information-on-new-safety-measures-to-be-introduced-in-the-coming-months** See also: Dreier J. W., Bjørk M., Alvestad S., et al. *Prenatal Exposure to Antiseizure Medication and Incidence of Childhood- and Adolescence-Onset Psychiatric Disorders.* JAMA Neurol. 80(6): pages 568 to 577 (2023). Available at: **https://jamanetwork.com/journals/jamaneurology/article-abstract/2803245**

212 Bromley R., Adab N., Bluett-Duncan M., Clayton-Smith J., Christensen J., Edwards K., Greenhalgh J., Hill R. A., Jackson C. F., Khanom S., McGinty R. N., Tudur Smith C., Pulman J., and Marson A.G., *Monotherapy treatment of epilepsy in pregnancy: congenital malformation outcomes in the child.* Cochrane Database Syst Rev. (2023). Available at: **https://pubmed.ncbi.nlm.nih.gov/37647086/**

213 Armstrong, K., Bluett-Duncan, M., Elsey, O., Khanom, S., Wittkowski, A. and Bromley, R. L., *Neurodevelopmental Outcomes in Individuals Exposed to Valproate in Utero and with Fetal Valproate Spectrum Disorder: A Systematic Review* (2023 – in submission, under review).

214 Armstrong, K., Bluett-Duncan, M., Elsey, O., Khanom, S., Wittkowski, A. and Bromley, R. L., *Neurodevelopmental Outcomes in Individuals Exposed to Valproate in Utero and with Fetal Valproate Spectrum Disorder: A Systematic Review* (2023 – in submission, under review).

215 Clayton-Smith J. et al., *Diagnosis and management of individuals with Fetal Valproate Spectrum Disorder; a consensus statement from the European Reference Network for Congenital Malformations and Intellectual Disability*, Orphanet Journal of Rare Diseases (2019).

216 Bluett-Duncan M., Astill D., Charbak R., Clayton-Smith J., Cole S., Cook P. A., Cozens J., Keely K., Morris J., Mukherjee R., Murphy E., Turnpenny P., Williams J., Wood A., Yates L., and Bromley R. L., *Neurodevelopmental outcomes in children and adults with Fetal Valproate Spectrum Disorder: A contribution from the ConcePTION project*', Neurotoxicology and Teratology, vol. 98 (2023). Available at: **https://doi.org/10.1016/j.ntt.2023.107201** The mean dose of valproate exposure for individuals with an FVSD diagnosis in this study was 1470 mg/day.

Annex B: Glossary

Congenital malformations are structural or functional anomalies that occur between conception and birth. Also called 'birth defects', these conditions may be identified before or at birth, or later in life.

Fetal Valproate Spectrum Disorder (FVSD) describes the range of signs and symptoms which occur because of exposure to valproate in the womb.

A wide range of physical anomalies occur at increased frequency, including spina bifida (when a baby's spine and spinal cord does not develop properly in the womb, causing a gap in the spine), major and minor limb abnormalities, oral clefting, cardiac defects, and joint laxity. Vision problems such as myopia (short-sightedness) and astigmatism are also common. Neurodevelopmental disorders associated with FVSD include reduced IQ, poorer language and motor development, increased rates of Autism Spectrum Disorder and Attention Deficit Hyperactivity Disorder.

Directly harmed are those:

- individuals whose mothers were taking valproate at any point during their pregnancy
- patients who have been implanted with pelvic mesh for the treatment of stress urinary incontinence or pelvic organ prolapse

Hormone pregnancy tests were a type of pregnancy test used in the UK from the 1950s to the 1970s. Since the late 1950s, concerns have been raised that they may cause abnormalities in a developing baby. Primodos was the most used hormone pregnancy test.

Indirectly harmed are those friends, families and loved ones of the directly harmed who have suffered emotionally, psychologically and/or physically as a result of the harm caused to that person.

Neurodevelopmental disorders are defined by ICD-11 as behavioural and cognitive disorders that arise during the developmental period that involve significant difficulties in the acquisition and execution of specific intellectual, motor, language or social functions. In this context, 'arising during the developmental period' is typically considered to mean that these disorders have their onset before the age of 18, regardless of the age that the individual first comes to clinical attention. Examples include intellectual disability, communication disorders; Autism Spectrum Disorder, Attention Deficit Hyperactivity Disorder and neurodevelopmental motor disorders.

Pelvic mesh is a medical device implanted to support pelvic organs including after pelvic organ prolapse and to manage stress urinary incontinence. It can be inserted trans-vaginally or trans-abdominally.

Pelvic organ prolapse (POP) is when one or more of the organs in the pelvis slip down from their normal position and bulge into the vagina. It can be the uterus (or if the woman has had a hysterectomy, the vaginal vault), bowel (including the rectum), bladder or top of the vagina.

Pregnancy Prevention Programme is a system designed to ensure that all women and girls of childbearing potential being treated with valproate medicines have been told and understand the risks of use in pregnancy, have signed a Risk Acknowledgement Form, are on highly effective contraception (if necessary) and see their specialist at least every year.

Rectal prolapse is when the end of the bowel (the rectum) slides out through the anus, forming a lump. A rectal prolapse may be full (or complete), partial or internal (where the rectum does not reach as far as the anus).

A **rectocele** occurs when the wall of tissue that separates the rectum from the vagina weakens or tears. When this happens, tissues or structures just behind the vaginal wall – in this case, the rectum – can bulge into the vagina. It is a type of pelvic organ prolapse.

Restorative practice is a term used to describe behaviours, interactions and approaches which help to build and maintain positive, healthy relationships, resolve difficulties and repair harm where there has been conflict.

(Annual) Risk Acknowledgement Form is a form that the Valproate Pregnancy Prevention Programme requires. It is used by clinicians at initiation and annual review of all girls and women of childbearing potential on valproate medicines.[1]

Stress urinary incontinence (SUI) is the involuntary leaking of urine when the bladder is under pressure for example, during coughing or laughing. SUI can be caused when the pelvic tissues, ligaments and muscles which support the bladder and urethra are weakened or damaged.

Teratogens/teratogenic are substances that produce a structural or functional change in the foetus or child when a pregnant woman is exposed to the substance.

Trans-abdominally is when pelvic mesh is inserted through an incision in the abdomen (tummy).

Trans-vaginally is when pelvic mesh is inserted through an incision in the vagina.

1 Annual Risk Acknowledgement Form. Available at: **https://assets.publishing.service.gov.uk/media/5cac898eed915d5d7318b646/Risk-acknowledgment.pdf**

Valproate is a licensed and effective treatment for epilepsy and bipolar disorder, introduced into the UK market in 1974. It is associated with a significant risk of birth defects and neurodevelopmental disorders in children born to women who take valproate during pregnancy – classing it as a teratogen. The term 'valproate' is preferred to 'sodium valproate' because it covers the variety of forms that the medicine can take, which includes sodium valproate and valproic acid.

Annex C:
Terms of reference (scope)

Patient Safety Commissioner –
Sodium Valproate and Pelvic Mesh Redress Specification

For each of the two interventions:

1. Seeking **views from those affected** about what redress would be appropriate – i.e., what form it should take and/or what levels of financial payments it should involve.

2. Further evidence and/or advice on the **size of the population** who have been harmed and how seriously. The lack of information here means that there is substantial uncertainty about potential redress costs. This could include overall estimates of people affected for each of the two interventions and also break this down in terms of the extent of harm across this population, i.e., giving an estimate of the scale of population with different needs. Advice could include further steps that could be taken by HMG or others to understand this better.

3. PSC's view of the **case for redress** and who this case would apply to within the population who has been harmed. For example, does the case apply to all those who have suffered harm consistent with the known issues, or only those in particular time periods or in particular circumstances.

4. PSC's view of **what form and level of redress** would be appropriate. In terms of form, what the purpose of any financial payments would be – e.g., to meet needs, to recognise pain, suffering or loss of amenity. It would be preferable if these were to include orders of magnitude rather than specific figures. Comparisons could be made to other redress payments made by governments, including those that relate to these two interventions, like the support to those harmed by pelvic mesh in Scotland. Advice should include consideration of value for money of any financial payments.

Annex D: Declarations of interest

Dr Henrietta Hughes, Patient Safety Commissioner

- Locum GP (remunerated)
- Governor, The Kings School Canterbury (non-remunerated)
- Chair, Childhood First (non-remunerated)
- Member of the Health Honours Committee (non-remunerated)
- Director, Accelerate Improvement Ltd (not trading)
- Fellow Royal College of General Practitioners (non-remunerated)
- Senior Fellow Faculty of Medical Leadership and Management (non-remunerated)
- Fellow Royal Society of Medicine (non-remunerated)
- Liveryman of the Society of Apothecaries (non-remunerated)
- Honorary Student, Christ Church, Oxford (non-remunerated)
- Member of the Women Health and Care Leaders Guiding Group (non-remunerated)
- Member of the Society for Assistance of Medical Families (non-remunerated)
- Member of the British Medical Association (non-remunerated)
- Diplomate of the Faculty of Family Planning (non-remunerated)
- Member of the NIHR SafetyNet Advisory Board (non-remunerated)
- Member of MedTech Strategy Programme Board (non-remunerated)
- Member of the National Patient Safety Committee (non-remunerated)

Dr Sonia Macleod, Expert Advisor

Category/Name	Relevant interest (if any)
Current employment	Advisor on the Patient Safety Commissioner redress project
Appointments (voluntary or otherwise) e.g. trusteeships, directorships, local authority membership and tribunals	Vice-Chair of Trustees and Director, The Crypt School, Gloucester (non-remunerated) Director, DRSM Consultancy Ltd
Membership of any professional bodies, special interest groups or mutual support organisations	Member of Lincoln's Inn (I am an unregistered barrister) (non-remunerated)
Any commercial/financial/ legal connection or interest in the pharmaceutical and medical devices industry sector or any other body or organisation of interest to the redress project	I run a research project on no-fault compensation for injuries due to COVID-19 vaccines at the Centre for Socio-Legal Studies, University of Oxford The project is funded by a grant from the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), whose members include Sanofi and J&J among others. This is an arm's-length grant agreement that has been assessed by the Oxford University research contracts team
Gifts or hospitality offered to you by external bodies and whether this was declined or accepted in the last 12 months	Guest of Luther Pendragon at the PR Week Awards 2023
Any contractual relationship with the redress project and/or parties of interest	Appointed as Expert Advisor by the Department of Health and Social Care
Any other interests that are not covered by the above	Appointed as a Special Advisor to the Health and Social Care Select Committee for its NHS Litigation Reform Inquiry and its IMMDS Review follow-up one-off session (December 2021 to January 2023)

Annex E: Breakdown of survey results in full

Patient Safety Commissioner redress survey results

- 571 responses (note: not all respondents answered every question).
- In the interests of completeness, the text of every question of the survey has been included below. However, questions which required the disclosure of free text as part of the response have not been analysed here to maintain patient confidentiality. These questions are shown in square brackets.
- Unless otherwise stated, all percentages are rounded to the nearest 1 decimal point.

1. **Is your response to this survey about pelvic mesh or valproate?**

Option	Number of responses	Percentage
Pelvic mesh	486	85.1%
Valproate	85	15.8%

2. **Which of the below statements apply to you?**

	Number of responses	Percentage
I am someone directly harmed by pelvic mesh or valproate (i.e., a person implanted with pelvic mesh or a person with Fetal Valproate Spectrum Disorder)	471	82.5%
I am responding on behalf of someone directly harmed by pelvic mesh or valproate	56	9.8%
I am someone indirectly harmed by pelvic mesh or valproate (i.e., someone who knows or has contact with a directly harmed individual. This category would include family and friends of directly harmed individuals)	69	12.1%
I am responding on behalf of an organisation	26	4.5%

3. **[If responding on behalf of an organisation, what is the name of your organisation? – free text question]**

4. In which country did you or the directly affected person first suffer harm?

Option	Number of responses	Percentage
England	178	78.8%
Wales	1	0.4%
Scotland	40	17.7%
Northern Ireland	5	2.2%
Elsewhere in the world	2	0.8%

5. [In which country did you or the directly affected person first suffer harm? – free text question if answer to Question 4 was 'elsewhere in the world']

6. [In what year did you or the directly affected person suffer the first harm? – free text question]

7. In which country do you currently live?

Option	Number of responses	Percentage
England	178	78.8%
Wales	2	0.8%
Scotland	39	17.3%
Northern Ireland	5	2.2%
Elsewhere in the world	2	0.8%

8. [As you selected 'elsewhere in the world' in the previous question, please specify in which country you currently live? – free text question]

9. Where in England do you currently live?

Option	Number of responses	Percentage
East of England	21	11.8%
London	7	3.9%
Midlands	62	34.8%
North East, Yorkshire and the Humber	25	14.0%
North West	11	6.2%
South East	28	15.7%
South West	24	13.5%

10. How has valproate or pelvic mesh impacted the following aspects of your life?

	Very negative impact	Quite a negative impact	Neither a positive nor negative impact	Quite a positive impact	Very positive impact	Unsure/do not know
Ability to work (voluntary or paid)	59.7%	25.3%	8.6%	1.8%	4.5%	0.0%
Ability to travel	43.9%	39.5%	11.2%	2.2%	2.7%	0.4%
Ability to carry out daily household tasks	48.4%	35.7%	10%	3.2%	2.7%	0.0%
Ability to care for others	46.6%	32.1%	14.5%	2.7%	3.2%	0.9%
Ability to socialise	51.4%	29.7%	13.1%	2.7%	2.7%	0.5%
My mental health and wellbeing	71.8%	19.1%	3.2%	0.9%	5%	0.0%
My relationship with partner, close friends or family	72.2%	15.7%	6.3%	1.3%	4.5%	0.0%
My financial situation	56.1%	16.7%	21.7%	0.9%	4.5%	0.0%
My access to, and experience of, education	33.3%	19.6%	37.4%	0.9%	1.8%	6.8%

11. [Overall, how satisfied are you with your life nowadays? – analysis of data not currently possible]

12. [Overall, to what extent do you feel that the things you do in your life are worthwhile? – analysis of data not currently possible]

13. "Receiving an individual apology (or apologies) is an important outcome of any redress process for me"

Option	Number of responses	Percentage
Strongly agree	335	59.7%
Agree	119	21.2%
Neither agree nor disagree (neutral)	86	15.3%
Disagree	11	2.0%
Strongly disagree	10	1.8%

14. [Who would you like an individual apology or apologies from, and why? – free text question]

15. If –

(A) legal representation were provided free of charge, and

(B) did not impact the value of the financial redress paid out to those harmed –

Do you agree that people accessing the scheme must have a legal representative?

Option	Number of responses	Percentage
Strongly agree	310	55.1%
Agree	114	20.2%
Neither agree nor disagree (neutral)	102	18.1%
Disagree	19	3.4%
Strongly disagree	18	3.2%

16. Should those who have already received compensation through legal means (for example through a medical negligence or product liability claim) be denied access to any redress scheme?

Option	Number of responses	Percentage
Yes	100	17.8%
No	305	54.2%
Don't know/no opinion	158	28.1%

17. If legal representation reduced the value of the financial redress available to those harmed – do you agree that people accessing the scheme must have a legal representative?

Option	Number of responses	Percentage
Strongly agree	140	24.8%
Agree	138	24.6%
Neither agree nor disagree (neutral)	159	28.3%
Disagree	72	12.7%
Strongly disagree	54	9.6%

18. To what extent do you agree or disagree with the following statements?

	Strongly agree	Agree	Neither agree nor disagree (neutral)	Disagree	Strongly disagree
"I still have unanswered questions about what happened to me and why it was allowed to happen"	69.5%	22.3%	6.4%	1.4%	0.4%
"Effective redress for me is more than just a financial award"	69.4%	20.7%	8.3%	0.7%	0.9%
"I want any redress scheme to allow me to tell my story and connect with other people affected"	49.6%	25.7%	21.6%	2.3%	0.9%
"I have confidence that changes have been made so that no one else is harmed by valproate or pelvic mesh again"	11.4%	8.0%	26.4%	22.3%	31.9%
"Any redress scheme should be run by a new body independent from government or the NHS"	65.9%	20.0%	11.0%	1.8%	1.4%
"I feel like the government has already provided me with an adequate apology"	1.2%	2.0%	20.6%	12.1%	64.1%

19. Out of the following possible categories of financial loss that a redress scheme could cover, please rank them from the most important to least important to you.

	Pain and suffering caused by the harm	Past and future loss of employment of the directly harmed – including loss of earning capacity	The injustice caused by the lack of information associated with pelvic mesh or valproate	Past and future cost of care (whether provided by an external provider or by family members)	Cost of meeting additional needs caused by the harm – equipment/ technology to assist with daily tasks, transport, home adaptations, etc.	The loss caused to indirectly harmed individuals (for example, loss of employment opportunities, loss of pension rights etc.)	Private medical treatment costs (for services not available or not suitably provided by the NHS)
1st choice	62%	6%	13%	6%	5%	4%	4%
2nd choice	17%	16%	25%	11%	10%	11%	9%
3rd choice	7%	18%	12%	21%	16%	16%	10%
4th choice	5%	20%	12%	17%	18%	15%	12%
5th choice	4%	14%	10%	20%	18%	19%	15%
6th choice	3%	13%	13%	15%	19%	19%	17%
7th choice	2%	12%	14%	12%	13%	16%	31%

*Rounded to the nearest whole %

20. One of the options we are looking at is whether the government should offer a one-off, fixed sum as an interim payment to people harmed by pelvic mesh or valproate.

    This payment would be based on some initial eligibility criteria and could be paid out while a more detailed scheme for further payments was being set up.

    This interim sum would not represent the full amount that people could choose to apply for.

    Do you support the award of an interim payment as described above?

Option	Number of responses	Percentage
Yes	396	69.8%
No	21	3.7%
Don't know	150	26.5%

21. [As you answered yes to the previous question – how much do you think this interim payment should be? – free text question]

22. [Why do think the interim payment should be set at that amount? – free text question]

23. To what extent do you agree or disagree with the following statements about possible financial redress?

	Strongly agree	Agree	Neither agree nor disagree (neutral)	Disagree	Strongly disagree
"Only the directly harmed individual (or their appointed representative) should be eligible for a financial award. This person can then use the funds to support others, if they so wish"	48.6%	24.7%	13.6%	8.8%	4.3%
"Financial awards made through the redress scheme should not affect my entitlement to social security benefits (for example, Universal Credit)"	80.7%	12.1%	4.8%	1.4%	0.9%
"The pool of eligible people needs to be as wide as possible – including the directly and indirectly harmed"	44.8%	24.9%	21.2%	5.9%	3.2%

24. Thinking about the times when you have interacted with different public bodies to access support and services for yourself or on behalf of others harmed, how satisfied were you with their knowledge and awareness of valproate or pelvic mesh and the harm that these interventions have caused?

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied	N/A – had no interaction
The Department for Work and Pensions (and their related bodies such as Job Centres)	2%	6%	25%	11%	35%	21%
Your local authority (for example in relation to Education, Health and Care Plans or disabled Blue Badges)	3%	9%	28%	9%	30%	21%
Places of education	1%	5%	29%	7%	25%	33%
Your employer	5%	9%	29%	7%	25%	33%
Your GP	7%	16%	20%	20%	32%	5%
Your local hospital or community health provider	4%	12%	18%	15%	44%	7%

*Rounded to the nearest whole %.

25. (For those answering in relation to pelvic mesh only – please skip if answering in relation to valproate) How satisfied are you with the NHS specialist mesh centres?

Option	Number of responses	Percentage
Very satisfied	64	13.5%
Somewhat satisfied	90	19.0%
Neither satisfied nor dissatisfied	75	15.9%
Somewhat dissatisfied	54	11.4%
Very dissatisfied	108	22.8%
N/A – I haven't accessed services at these centres	82	17.3%

26. [Why is the establishment of a redress scheme important to you and how would implementation of a scheme help you to move forward in your life? – free text question]

27. [What is your date of birth? – free text question]

28. Do you have any physical or mental health conditions or illness lasting or expected to last 12 months or more?

Option	Number of responses	Percentage
Yes	441	79.5%
No	58	10.5%
Don't know	56	10.1%

29. What is your ethnic group?

Option	Number of responses	Percentage
Asian or Asian British	6	1.2%
British, Black British, Caribbean or African	2	0.4%
Mixed or multiple ethnic groups	2	0.4%
White	538	95.7%
Prefer not to say	8	1.4%
Other	6	1.2%

30. What is your religion?

Option	Number of responses	Percentage
No religion	189	33.6%
Christian (including Church of England, Catholic, Protestant and all other Christian denominations)	331	58.8%
Buddhist	2	0.4%
Hindu	2	0.4%
Jewish	2	0.4%
Muslim	3	0.5%
Sikh	0	0.0%
Prefer not to say	27	4.8%
Other	7	1.2%

31. Which of the following options best describes how you think of yourself?

Option	Number of responses	Percentage
Heterosexual or straight	527	93.1%
Gay or lesbian	1	0.2%
Bisexual	6	1.1%
Prefer not to say	28	4.9%
Other	4	0.7%

32. What is your sex?

Option	Number of responses	Percentage
Male	34	6.0%
Female	529	93.1%
Prefer not to say	5	0.9%

33. Is the gender you identify with the same as your sex registered at birth?

Option	Number of responses	Percentage
Yes	556	98.4%
No	3	0.5%
Prefer not to say	4	0.7%
Other	2	0.4%

Annex F: List of people the team met with

Patient representative groups

We met with the following patient groups and a number of individual patients who approached us directly (who we are not naming to maintain patient confidentiality).

Action for Mesh Injured Patients

FACSaware

INFACT National Valproate Campaign

Mesh UK Charitable Trust

OACS (Organisation for Anti-Convulsant Syndrome)

Rectopexy Mesh Victims and Support

Sling the Mesh

Valproate Victims

Other individuals and organisations

Interested individuals

Dr Wael Agur

David Body

Dr Rebecca Bromley

Georgie Forshall

Sir Robert Francis KC

Dr Sam Gower

Ed Glasgow

Bozena Michalowska Howells

Professor Swati Jha

Professor Georgina Jones

Dr Sonia Khanom

Interested individuals (continued)

Mollie Price

Professor Stephen Radley

Professor Peter Turnpenny

Jo Wailing

Interested organisations

Cabinet Office

Department for Education

Department for Work and Pensions

Epilepsy Society

Hugh James Solicitors

NHS Resolution

Restorative Thinking

Sanofi

Scottish Government

The Thalidomide Trust

We also approached Johnson and Johnson for a meeting. They declined our invitation but provided the below response:

> **Thank you for reaching out to us and for your patience whilst we have looked into your request. Safety is the primary focus of everything we do across our entire product portfolio and is a principle that we have been committed to since our founding over 130 years ago. We believe that Medical Devices registries can play an important role in ensuring that safety remains the primary focus, as they enable the assessment of the performance of a device when it goes to market, supporting post-market surveillance. The registries will inform future quality and regulatory frameworks and ongoing research and development. With that said and whilst we appreciate the opportunity, we had previously replied to the inquiry (attached) and at present, have nothing further we would like to add.**[1]

1 The attachment referred to is the document published here: IMMDS Written Evidence Manufacturers of Pelvic Mesh (2018). Available at: **https://www.immdsreview.org.uk/downloads/Evidence/FOR%20PUBLICATION%20-%20Manufacturers%20of%20Pelvic%20Mesh.pdf**

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