Patient Safety Commissioner
Listening to Patients

Annual Report 2025–26

Patient Safety Commissioner

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Foreword

Prof Mary Dixon-Woods

This report appears at a time when patient safety is rightly under intense scrutiny. Regulation, standards and professional expertise all matter. But they are not enough on their own. Safety also depends on whether healthcare systems are prepared to listen to patients and families, to recognise and learn from patterns of harm, and to ensure those harms are not repeated. What stands out in this report is the distinctive role played by the Patient Safety Commissioner: not as another institutional player, but as an independent and authoritative point of interpretation, challenge, and advocacy. The role is important in creating the conditions for risks to be brought into focus, for difficult truths to be surfaced, for patterns to be recognised across individual cases, and for patient concerns to be translated into pressure for practical change.

The report is clear about how the Commissioner is able to expose what might otherwise remain obscured and to focus attention on issues that might otherwise be prone to drift, as for those harmed by the use of valproate in pregnancy and pelvic mesh. Particularly striking is the demonstration of how patient insight can drive action. The Commissioner's recommendations, grounded as always in patient experience, have already contributed to improvements, including better responses to deterioration through Martha's Rule.

Looking ahead, emerging areas such as artificial intelligence make the need for a proactive approach to patient safety ever more imperative. Innovation offers real promise, but also new risks that need to be identified and managed if the benefits are to be realised safely and equitably. The Commissioner's contribution here has been invaluable: she has insisted that patient safety, transparency and public confidence are not secondary considerations, but preconditions for responsible progress. Rigorous evaluation during design and deployment, and continuous monitoring and learning over the long-term, will be essential. And throughout, patients must remain at the centre, not the margins.

This report documents important achievements, but it is not just a catalogue of activity. It reminds us that patient safety depends on clarity of purpose, willingness to confront uncomfortable truths, and determination to turn learning, however painfully won, into change. In a healthcare system as complex and fragmented as ours, where responsibility is dispersed across multiple organisations and interests, the combination of independence, visibility, advocacy and persistence that characterises the Commissioner's work is a great asset. It represents a key safeguard against avoidable harm being overlooked, repeated or quietly normalised.

Professor Mary Dixon-Woods FAcSS FMedSci
Health Foundation Professor of Healthcare Improvement Studies
Director, THIS Institute, Department of Public Health and Primary Care,
University of Cambridge

Introduction

Prof Henrietta Hughes

It is with a strong sense of purpose and optimism that I introduce this Annual Report for 2025–26. This year has been marked by meaningful progress, renewed momentum and an unwavering commitment to improving the safety of medicines and medical devices for patients across England. At the heart of our work remains a simple but powerful principle: patients must be heard and their experiences must translate into safer care for all.

I am deeply honoured to have been reappointed for a second term as Patient Safety Commissioner for England. This renewed mandate reflects not only the importance of the role, but also the growing recognition that patient voices are central to effective safety systems. It provides an opportunity to build on the strong foundations established in my first term – strengthening relationships, accelerating reform and embedding a culture of listening and learning across the healthcare system. I would like to express my sincere thanks to everyone who has contributed to the work of the Patient Safety Commissioner function, including patients and families, Ministers and system partners, Advisory Group members, my sponsor team, the AI Commission team and, with heartfelt thanks to the Patient Safety Commissioner team.

Over the past year, we have continued to focus on medicines and medical devices – areas where harm can be profound, systemic and long-lasting. Patients and families affected by adverse outcomes have consistently told us that their concerns were too often overlooked, their experiences dismissed and their routes to redress unclear or inaccessible. Addressing these failings remains at the core of our mission.

A significant milestone this year has been the continued pressure on the Government to deliver redress for those harmed by valproate and pelvic mesh. These interventions have changed the lives of many patients and families, and their experiences have come to symbolise the urgent need for a more responsive and accountable system. While we recognise that meaningful redress takes time to design and implement, there has been tangible movement toward acknowledging harm and developing non-financial redress. For the first time, this year, I used my powers to request information and secured a commitment from the Secretary of State to progress a decision for financial redress within this Parliament. We have worked closely with government,

system partners and, critically, affected patient groups to ensure that solutions are grounded in lived experience. At the time of writing, my letter to the Prime Minister of 3 March 2026 remains unanswered and I have written again using my powers to request information about meetings, correspondence and ministerial briefings on the subject of financial redress.

This year, our work has evolved alongside rapid advances in technology, particularly in artificial intelligence (AI). The establishment of the National Commission into the Regulation of AI in Healthcare has been a pivotal development in this regard. As healthcare increasingly integrates AI-driven tools into decision-making, diagnosis and treatment, the safety implications are profound. The Commission offers a vital platform to examine these challenges collaboratively, bringing together expertise from across disciplines to ensure that innovation does not outpace safeguards. As the Deputy Chair of the AI Commission and Chair of the Health Systems Working Group, I am committed to ensuring that patients' perspectives are integral to these conversations. Technology must enhance safety, not compromise it, and proactive oversight is essential to achieving that balance.

This year also marked an important organisational development, with a change of sponsor team at the Department of Health and Social Care (DHSC) and hosting of the Office of the Patient Safety Commissioner (PSC) by the Medicines and Healthcare products Regulatory Agency (MHRA). From 2026–27 day-to-day financial management of the PSC budget will be undertaken within the MHRA's financial systems and controls, while funding will continue to be provided by DHSC.

This hosting arrangement provides operational support, while preserving the independence necessary to advocate effectively on behalf of patients. The relationship enables close working with regulatory processes, ensuring that patient insights inform safety monitoring and decision-making in real time. At the same time, our independence ensures that we can act as a strategic enabler, providing constructive challenge, highlighting gaps and supporting improvement where needed.

In September 2025, we published our Impact Paper – an important moment of reflection on the journey so far. The report highlighted the difference my office has made since its inception: amplifying patient voices, influencing policy change and raising awareness of systemic safety issues. It also captured the breadth and depth of the concerns shared with us, reinforcing the importance of our role as a conduit between patients and the system. Crucially, the Impact Paper was not only about looking back, it was about identifying what must come next. It underscored the need for sustained effort, deeper collaboration and continued focus on outcomes that matter to patients.

Central to our approach has been engagement – ensuring that the voices we hear are diverse, representative and reflective of real-world experience. This year, the term of the first Advisory Group came to an end, and we plan to bring

together a renewed cohort of expert members to provide invaluable insight and constructive challenge, including representation from the devolved nations. The refreshed group will strengthen our ability to understand emerging issues, test our thinking and remain grounded in patient reality.

Listening, however, is only the first step. Acting on what we hear is what drives change. Over the past year, we have continued to advocate for clearer communication, improved reporting systems and more joined-up approaches to safety. Patients have told us that navigating existing processes can be confusing and exhausting – particularly when they are already dealing with harm. We have worked to highlight these barriers and promote solutions that simplify pathways, enhance transparency and ensure accountability. We welcome the new Patient Experience Director position, which has been established by DHSC as part of the 10 Year Health Plan and look forward to working collaboratively with them.

Looking ahead, we are preparing to publish a refreshed strategy that will guide our work in the coming years. This strategy will build on what we have learned, setting out a focused and ambitious vision for the future. It will reflect the evolving landscape – recognising the growing role of digital health and AI, the need for robust surveillance systems and the importance of addressing health inequalities in patient safety. Above all, it will reaffirm our commitment to placing patients at the centre of every decision.

The challenges in medicines and medical device safety are complex, but they are not insurmountable. Progress depends on collaboration, between regulators, clinicians, manufacturers, policymakers and, most importantly, patients. Over the past year, we have seen encouraging signs of this collective effort, with increasing openness to learning from patient experience and a shared determination to do better.

This Annual Report documents the work undertaken over the past 12 months, the progress achieved and the challenges that remain. It reflects the accounts of those who have come forward to share their experiences, often at great personal cost, in the hope that others will not suffer the same harm. Their courage continues to inspire and guide everything we do.

As we move forward into the next phase of our work, I remain optimistic. There is growing recognition that patient safety is not solely a clinical issue, but a system-wide responsibility. There is increasing willingness to listen, to learn and to act. And there is a shared understanding that safety must be proactive, not reactive, anticipating risks before harm occurs.

My reappointment provides continuity, but it also brings renewed responsibility. I am committed to using this second term to accelerate progress, deepen impact and ensure that patient voices drive meaningful, lasting change.

Together, we can create a healthcare system where medicines and medical devices are not only innovative and effective, but consistently safe and where every patient knows that their voice matters.

I commend this report to you and look forward to the continued journey ahead.

Prof Henrietta Hughes FRCGP SFFMLM OBE
Patient Safety Commissioner for England

About the Patient Safety Commissioner

The Patient Safety Commissioner for England is an independent statutory role, established under the Medicines and Medical Devices Act 2021. In 2022, Prof Henrietta Hughes OBE was appointed in the role of the first Patient Safety Commissioner in the world after a recommendation from the Independent Medicines and Medical Devices Safety Review in 2020, *First Do No Harm*, conducted by Baroness Cumberlege.

The review called for a Patient Safety Commissioner to be appointed "to be the patients' port of call, the listener, the advocate, that holds the system to account, monitors trends, and demands action."

Research shows that an estimated 237 million medication errors occur each year in England. While around 72% have little or no potential for harm, approximately 66 million are potentially clinically significant. These errors are estimated to cause or contribute to 1,708 deaths annually, with avoidable harm costing the NHS approximately £98.5 million a year.

Acting as an independent champion for patients, the Patient Safety Commissioner leads a drive to improve the safety of medicines and medical devices by ensuring that patient voices are at the heart of the design and delivery of healthcare in England.

The Commissioner is directly accountable to Parliament and operates independently of government and the health system. The Commissioner's statutory powers include:

- The authority to require information from relevant organisations, which are legally obliged to comply
- The ability to publish reports and recommendations, to which recipients must respond within deadlines set by the Commissioner.

While the Commissioner cannot intervene in individual cases of patient harm, she may use such cases to identify and highlight systemic issues.

Transition to MHRA

Following the **Dash Review** recommendations, the Office of the Patient Safety Commissioner is hosted by the MHRA, while retaining sponsorship by DHSC and accountability to Parliament.

The PSC remains fully independent in its statutory functions, including setting priorities, issuing advice and reporting publicly. This independence is fundamental to maintaining trust and enables the Commissioner to provide impartial challenge on behalf of patients.

Being hosted by the MHRA presents a real strategic opportunity. It creates a close and constructive connection between independent patient insight and regulatory leadership. It supports earlier understanding of patient concerns, better communication and stronger assurance, while fully preserving the independence and accountability of the Commissioner.

It enables the Commissioner to engage with regulatory priorities and constraints, ensuring that patient safety insight is informed, proportionate and actionable. Even at this early stage, it is clear that this arrangement directly supports the MHRA in delivering its objectives.

The Commissioner welcomes the MHRA's continued commitment to valuing patient and public voices and the opportunity created by hosting the Office to embed that commitment in practice.

"The Patient Safety Commissioner plays a vital role in ensuring that the experiences of patients are heard and acted upon across the healthcare system. Patient perspectives are essential in helping us understand the real-world impact of our decisions, build trust and ensure that regulation delivers for the people it is designed to serve.

"This year has marked an important milestone, as the MHRA began hosting the Office of the Patient Safety Commissioner. While the Commissioner remains fully independent, this first year of hosting has strengthened opportunities for collaboration and reinforced the value of bringing patient voices into our work.

Lawrence Tallon, MHRA Chief Executive

"That impact has been particularly evident through the National Commission into the Regulation of AI in Healthcare. As Deputy Chair, Henrietta has played a vital role in ensuring patient voices are an integral part of the conversation, helping to bring lived experience into discussions about the future of AI in healthcare.

“I look forward to continuing our collaboration with the Patient Safety Commissioner to ensure patient experiences are heard, understood and reflected in our work.”

Lawrence Tallon, MHRA Chief Executive

Progress against recommendations

The Patient Safety Commissioner has the power to make recommendations to improve patient safety across medicines and medical devices. These focus on how the system listens to patient experiences, monitors treatments in practice, supports informed decision making, promotes clear communication and better coordination between organisations and acts on concerns. They provide a practical framework for safer care, continuous learning and stronger trust between patients and the healthcare system.

This section of the report sets the context and tracks progress against these recommendations, highlighting where action has been taken and where further work is needed.

The full details of the Commissioner's recommendations are published on the **PSC website**.

1. Justice for those harmed by pelvic mesh and valproate

Harm caused by pelvic mesh and valproate represent some of the most serious patient safety failures in recent NHS history. Both interventions caused avoidable, life-changing harm on a large scale, with patients not receiving the right information to consent to treatment, flaws in post-market surveillance and patients' concerns being dismissed and denied.

Valproate, while a vital treatment for some patients with epilepsy, migraines and bipolar disorder, has caused devastating harm to the unborn child when taken during pregnancy. Up to 20,000 children were exposed to valproate between 1973 and 2017 in England alone. The complex and lifelong nature of the harm associated with prenatal exposure means that today thousands of children, young people and adults are unable to live independently. Many parents have been forced to give up employment in order to provide full-time care, with profound financial and emotional consequences for entire families.

Pelvic mesh procedures, used to treat stress urinary incontinence and pelvic organ prolapse, are estimated to have harmed around 10,000 patients. Patients have experienced severe complications, including debilitating chronic pain, loss of mobility and significant psychological trauma. For many, this has resulted in the loss of careers, livelihoods, independence and relationships.

Legal data shows the difficulty of securing redress through courts: of 1,252 mesh-related legal cases (2014–2024), only 356 resulted in damages, while 678 concluded without compensation.

The 2020 *First Do No Harm* review highlighted these harms as avoidable and exacerbated by a system that failed to act on patient concerns.

The 2024 *Hughes Report* proposed:

- A two-stage financial redress scheme co-designed with patients, consisting of an initial fixed interim payment and a subsequent tailored compensation scheme based on individual need
- Non-financial redress to provide better care and support to patients and families affected by these interventions.

The *First Do No Harm* review made a compelling case for redress. The Government accepted that case and asked the Patient Safety Commissioner to set out how it could be delivered and the urgency with which it was needed in the Hughes Report.

More than two years later, at the time of writing, the Government has yet to provide a substantive response to the recommendations in the Hughes report or a clear timetable for delivering redress.

A cruel emotional rollercoaster

Patients have consistently told the Commissioner that delays in redress are compounding the original harm, creating a "cruel emotional rollercoaster" for all those affected and their families.

Redress is about recognition, accountability and restoring dignity, not just financial payment. It is a core patient safety issue, signalling whether the system acknowledges harm, learns from failure and restores trust after years of pain.

The data from the *Hughes Report* is stark and, sadly, still relevant. Patients face severe financial hardship, escalating care costs, and profound mental health distress driven by a lack of recognition and delayed governmental action.

- 85% unable to work
- 73% experience financial hardship
- 91% battle with deteriorating mental health
- 88% feel impact on relationships

"Acknowledgement alone does not provide justice to the thousands of patients and families who have been harmed. Patients' lives don't grind to a halt while Government departments debate jurisdiction and timelines."
Prof Henrietta Hughes

First use of statutory powers and escalation to No. 10

During 2025–26, the Commissioner actively pursued answers to her recommendations for redress through sustained action:

- First use of statutory powers under the Medicines and Medical Devices Act in Oct 2025, writing to the Parliamentary Under-Secretary of State for Health Innovation and Safety at the time, Dr Zubir Ahmed, to demand government transparency
- Public challenge highlighting delays as 'unacceptable', ensuring inaction remained visible and contestable, rather than normalised, with media coverage in the Sunday Times, the Guardian, Independent, ITV News and the BMJ in January of 2026
- Escalation to No.10 and the Prime Minister in March 2026, calling for a clear timetable for the delivery of financial redress.

System response

The Patient Safety Commissioner welcomed the former Minister's for Health Innovation and Safety response to her request for information and within the timescale specified.

Detail was offered on non-financial redress initiatives including:

- A pilot project on fetal exposure to medicine in Newcastle and Manchester
- An internal audit of specialist mesh centres in England
- Research to identify the outcomes that matter to patients after surgery for prolapse, incontinence and mesh complications.

While some progress was made on non-financial redress, the letter from the former Minister made it clear that the Department of Health and Social Care does not hold the authority to deliver financial compensation, which rests with the Treasury and No.10. As of the end of the reporting period, no confirmed plans for financial redress were in place.

With Emma Murphy and Janet Williams from INFACT in Westminster

Between April 2025 and March 2026, issues relating to pelvic mesh and valproate were subject to significant parliamentary scrutiny, with over 150 written parliamentary questions tabled to Ministers. These covered a wide range of concerns, including patient safety, clinical support and – critically – progress on redress following the Hughes Report.

On 11 February 2026, a Westminster Hall debate marking the second anniversary of the Hughes Report, led by Sarah Green MP, provided a further opportunity for Parliament to scrutinise progress on redress for those harmed by pelvic mesh and valproate.

Opening the debate, Sarah Green highlighted the continued absence of a Government response, noting that two years on, no compensation scheme had been implemented and no timeline had been set, despite clear recommendations.

With Kath Sansom from Sling the Mesh

Members from across the House reflected on the significant and ongoing impact on patients and families, emphasising both the scale of avoidable harm and the urgency of delivering justice. The debate reinforced cross-party concern about delays and called for the Government to move beyond consideration to action, underlining the sustained parliamentary pressure to establish a redress scheme and provide financial compensation.

Professor Hughes extends her heartfelt thanks to all campaigners and their families for their tireless efforts, unwavering commitment and inspiring resolve in securing justice.

Secretary of State for Health and Social Care commitment

Following parliamentary and media attention, the former Secretary of State for Health and Social Care, Wes Streeting, reaffirmed the Government's commitment to progressing a decision on financial redress within the current Parliament, during an interview on ITV on 13 February and in a subsequent letter to the Commissioner in March 2026.

Stark lack of Government response

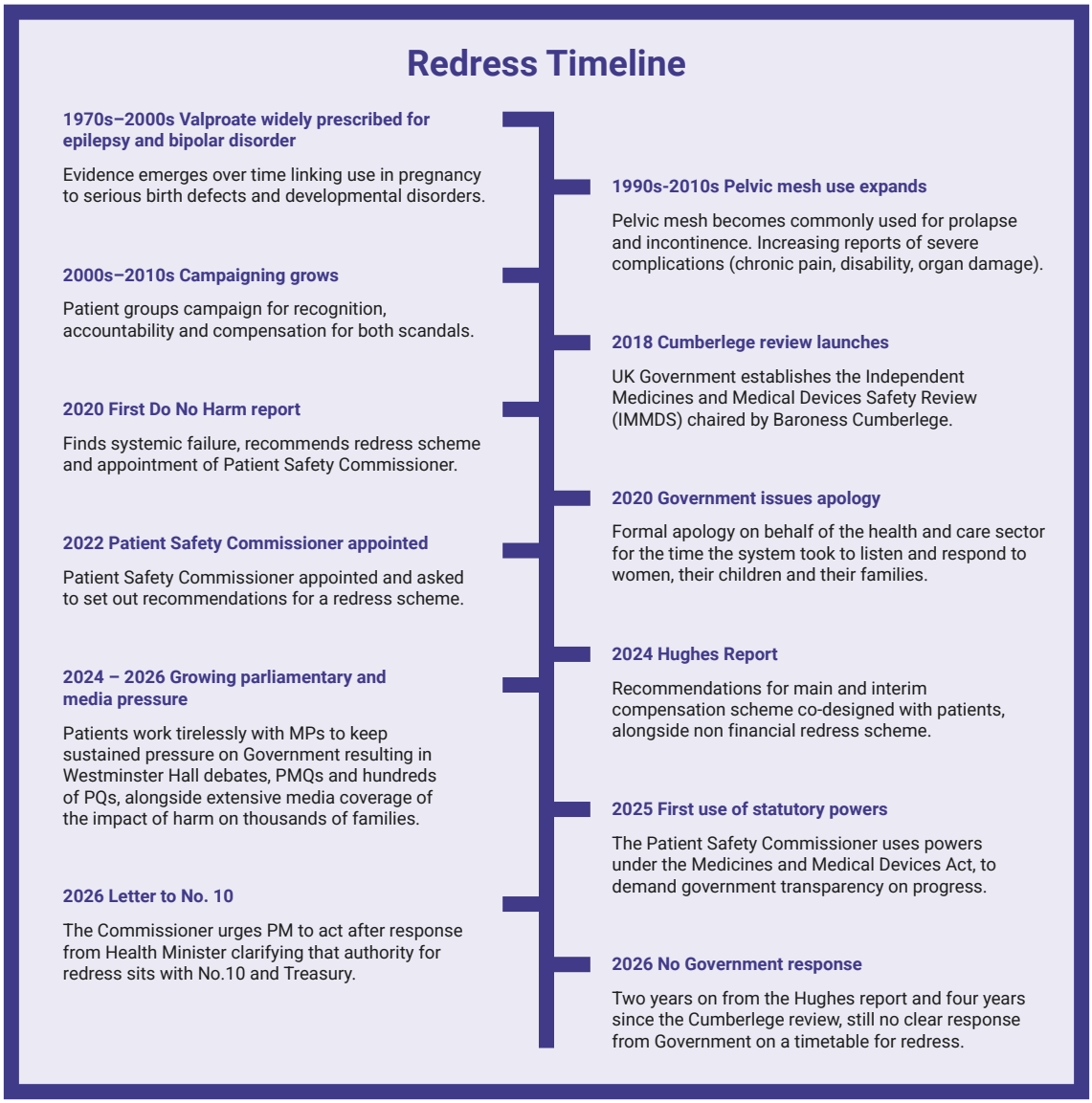
At the time of writing, the Government is yet to announce a redress scheme or a timeline for providing a substantive response to the recommendations made in the Hughes report.

Clarity of purpose and urgency of action are essential when it comes to addressing risks to patient safety and past harm caused by medicines and medical devices.

There is an urgent moral imperative to address past harm. Delivering redress is fundamental to keeping people safe – without accountability, failures persist, lessons go unlearned and patients remain at risk.

The Government must now act decisively to implement a fair, timely and accessible system of financial compensation for those harmed by valproate and pelvic mesh.

Key Timeline



2. Safer use of potent teratogens

The issue of teratogenic medicines provides a clear example of the impact that patient insight can have on the Commissioner's priorities and recommendations.

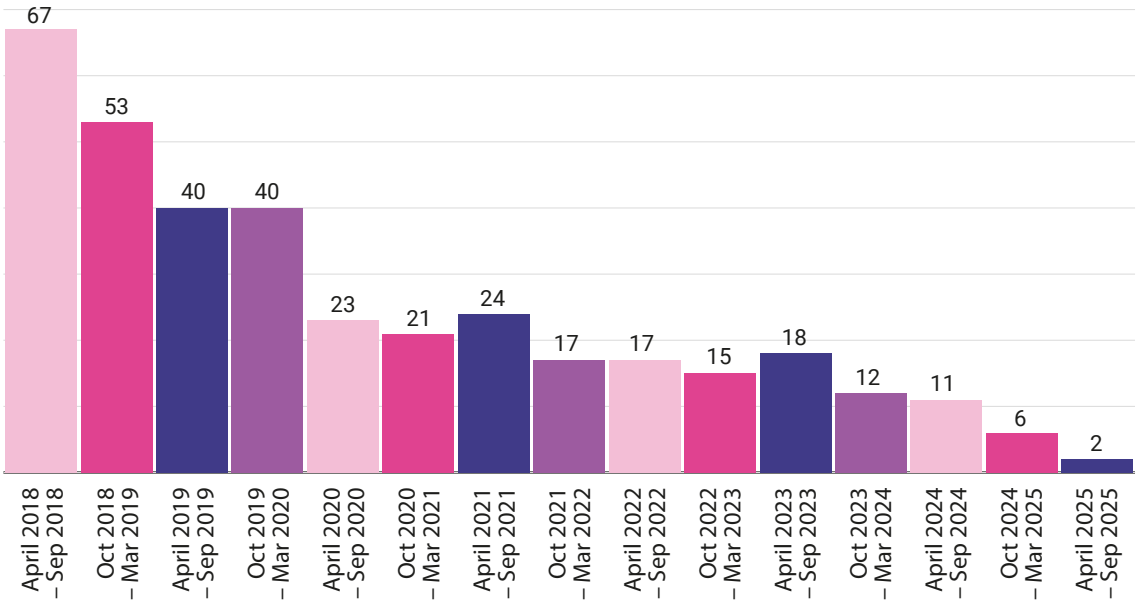
Patients consistently highlighted gaps in the information provided about the most potent teratogenic medicines including valproate, topiramate and isotretinoin, caused by fragmented care across multiple providers. At the time of the Commissioner's appointment in 2022, 17 women (within a six-

month period) were still being prescribed valproate during pregnancy despite all the known risks. These issues were longstanding, but without a national recommendation there was no clear imperative to act.

The Commissioner's 2023 recommendation to NHS England on the safe use of the most potent teratogens, which has now been fully delivered, created focus and drove systemwide action to better protect patients.

This work has resulted in a significant and welcome strengthening of safeguards for patients. What began as a targeted focus on improving the safe prescribing of valproate has now been successfully extended to other potent teratogens, including topiramate. The learning from this programme is being applied more widely across Integrated Care Systems, supporting a more consistent approach across the patient pathway and reducing variation in practice.

Number of females prescribed valproate during pregnancy within a 6 month period



NHS England, *Medicines in pregnancy: During pregnancy facts dashboard* **https://tabanalytics.data.england.nhs.uk/t/Public/views/MedsPreg/DuringPregFacts**

A key priority is ensuring that patients and those who support them, have clear, accessible information about these medicines and the requirement for prescribers to discuss pregnancy prevention programmes. This must be underpinned by a joined up approach to care, with information flowing effectively between services. This is essential to supporting reproductive choice, so that patients are fully informed and able to make the right decisions about their care.

Extending this focus beyond valproate marks an important step forward in reducing risk and strengthening patient safety. It demonstrates how targeted action, informed by patient experience, can lead to meaningful system-wide improvement.

The Commissioner welcomes NHS England's commitment in responding to this Recommendation and its delivery to completion. This progress in line with the Patient Safety Principles, reflects the value of listening to patients and acting decisively to prevent harm, ensuring that improvements in safety are sustained across the healthcare system.

3. The life-saving impact of Martha's Rule

Martha's Rule recognises that those who know the patient best may be the first to notice changes that could be an early sign of deterioration and the importance of listening to and acting on the concerns of patients, families and carers. It is being implemented in both adult and children's inpatient settings in England.

The Patient Safety Commissioner has played a central role in developing the policy and supporting the implementation of Martha's Rule across the NHS and independent sector, working collaboratively as Chair of the Oversight Group alongside Martha's family and system leaders.

Through engagement with a wide range of global partners, the Commissioner has shared patient-centred safety insights and promoted learning to support safer healthcare systems internationally. This included participation in the International Society for Quality in Health Care (ISQua), the IHI–BMJ International Forum on Quality and Safety in Healthcare in Utrecht and liaising with European health providers to help change culture in their organisations.

Early data from NHS England's Patient Safety Team demonstrates the value and impact of Martha's Rule in practice. Between September 2024 and March 2026, 13,481 escalation calls were made, with the majority (72%) initiated through the family and carer escalation route. Of these, 4,336 calls (32%) related to acute deterioration.

Inclusion of Martha's Rule in the NHS Standard Contract means it is now a mandated requirement for NHS-funded providers to implement, with organisations contractually obliged to comply, while as a core standard it represents an essential, nationally defined expectation that must be consistently met to ensure safe, high-quality and equitable care across the NHS.

Martha's Rule demonstrates how listening to patients and their families and carers can accelerate the translation of patient voice into policy, piloting and ultimately into standard practice across the NHS.

The Commissioner wishes to express her profound gratitude to Martha's parents for their dedication and relentless campaigning and welcomes the unwavering commitment of healthcare providers across England in delivering Martha's Rule, under the leadership of the National Director of Patient Safety in NHSE and the National Patient Safety team, in partnership with the National Nursing Directorate.

4. Improving the effectiveness of patient information

The Commissioner made a recommendation in the **Safety Gap Report** in March 2025 to the Association of the British Pharmaceutical Industry (ABPI), MHRA and DHSC to restart work to digitise paper-based patient information leaflets via the existing UK Electronic Patient Information Task Force (ePIL). The Commissioner also recommended that as part of this restart, ePIL, working with patients, should examine how to maximise the benefits of this work for patients with sensory impairment.

In response, the MHRA Improving Patient Information project, launched in May 2025, a multi-year project aiming to modernise how medicine product information is delivered, making it more accessible, trusted and fit for the future. Since then, it has worked closely with stakeholders across the UK health system including patient groups and charities to understand current challenges with patient information leaflets (PILs). The project will explore digital approaches and alternatives to improve the provision of PILs.

As part of the first phase of work, the MHRA has commissioned independent research and conducted extensive stakeholder engagement with over 250 patients, healthcare professionals and partners to scope policy approaches to improve patient information related to medicinal products. These approaches will enable patients to receive information that is clear, concise and accessible and ensure they are equipped with information to support their own healthcare choices.

Work with the UK Electronic Patient Information (ePI) Task Force has continued to explore digital opportunities to improve the effectiveness of patient information. Additionally, the MHRA has committed to work alongside patients and the public and spearhead a fully inclusive approach to improving PILs, including information used by those with sensory impairment.

A multi-stakeholder workshop, held in December 2025, achieved alignment on key policy options and an action plan for phase two. The Patient Safety Commissioner for England was a keynote speaker at the workshop and spoke passionately about expanding the range of options of how patients and the public can access information so they can make the right choices about their healthcare.

Further information on the project, including the five design principles, can be found on the MHRA website: **https://www.gov.uk/government/publications/improving-patient-information**

Demonstrating impact and accountability

The Patient Safety Commissioner strengthened transparency and accountability, in line with the **Patient Safety Principles**, by publishing a comprehensive Impact Paper in September 2025. The report sets out the tangible difference the role has made since its establishment in 2022, through collaboration with patients and families, Ministers, health leaders and officials.

This paper represents a significant milestone in articulating how the first ever Patient Safety Commissioner in the world has driven improvements in the safety of medicines and medical devices, ensuring that vital recommendations are not ignored or lost in bureaucracy, while elevating the role of patient voice across the healthcare system.

The Impact Paper brought together evidence of systemwide influence, highlighting how the Commissioner has shaped national policy, contributed to major public inquiries, including the Infected Blood and COVID19 inquiries; and supported changes in clinical practice through close engagement with regulators and partners.

It also captured measurable progress, including:

- The introduction and widespread adoption of the Patient Safety Principles across regulators, providers and industry
- Strengthening approaches to informed consent through the promotion of the BRAN framework
- Recommendations on options for redress for those harmed by valproate and pelvic mesh, Martha's Rule, the safety and accessibility of medicines and medical devices for those with sensory impairment and the safe use of the most potent teratogens.

The report further demonstrated the growing use of patient insight to identify and prevent harm. For example, concerns were raised about the dispensing of valproate without appropriate safety warnings, leading to rapid regulatory action and a national alert to pharmacists. This work also contributed to updated guidance on medicines such as isotretinoin and fluoroquinolones.

The publication of the paper provided a clear and accessible account of how listening to patients is driving safer care, better outcomes and more efficient use of resources, at a time of uncertainty about the future of the Commissioner's role, when her second term had not yet been confirmed.

By setting out both achievements and ongoing challenges, the Commissioner reinforced her commitment to openness, learning and continuous improvement, while establishing a strong evidence base to guide future priorities.

The full paper can be found on the PSC website:
https://www.patientsafetycommissioner.org.uk/wp-content/uploads/2025/09/PSC-Impact-Paper-1-1.pdf

Patient and public insight and emerging safety issues

The Office of the Patient Safety Commissioner is informed directly by what patients, family members, carers, clinicians, advocacy organisations, researchers and parliamentarians tell us. This engagement provides a rich and unfiltered source of insight into patient safety concerns across the system. The Commissioner and her team are grateful to everyone who has contacted the Office with their valuable insights and questions.

These accounts often reflect lived experience of harm, barriers encountered in care and gaps in safety mechanisms. These insights offer early signals of emerging risks as well as deeper understanding of persistent systemic challenges. As such, they play a critical role in informing the PSC's priorities, shaping engagement with system partners and identifying where patient voice is not being adequately heard.

Across all themes, patients consistently described feeling unheard within existing systems. What people told the Commissioner in the last year highlighted difficulties navigating complaints processes, lack of acknowledgement of harm and barriers to accessing appropriate care or redress. There is a strong perception that patients must self-advocate extensively to secure attention or action.

There was growing public engagement with new patient safety mechanisms, particularly Martha's Rule. Questions from patients, clinicians and organisations both in England and overseas focused on how it will work in practice, indicating both awareness and expectation and a desire for more accessible and responsive escalation routes within care settings.

More broadly, stakeholders, including patients, clinicians and organisations, expressed strong interest in contributing to system learning. This included engagement with the Patient Safety Principles, the National Commission for the Regulation of AI in Healthcare, governance and how safety lessons could be embedded across healthcare systems.

Key insights from patients and families show unresolved harm, difficulties accessing care and challenges navigating the health system. Alongside this is a strong desire for recognition, accountability and real change, including clearer routes to redress, better safety oversight and assurance that patient harm informs future policy and practice.

Key themes:

- **Lived experience of harm dominates.** Many correspondents describe long-term physical, psychological and financial impacts from treatments (especially mesh, medicines and implants). These are often harrowing, personal accounts used to support calls for recognition and change.
- **Ongoing frustration with redress and accountability.** A strong theme is lack of clarity, pace and perceived fairness in compensation or redress schemes, particularly for pelvic mesh and valproate. Patients frequently follow up repeatedly, indicating loss of confidence in system responsiveness.
- **Feeling unheard within the healthcare system.** Recurrent narratives highlight dismissal of symptoms, poor communication and barriers in complaints processes. Many patients turn to the PSC after exhausting NHS and regulatory routes, suggesting gaps in trust and escalation pathways.
- **Demand for better medicines and device safety oversight.** Patients emphasise failure of consent processes, under-recognition of side effects and limitations of reporting systems (e.g. Yellow Card). There is clear appetite for stronger regulation and proactive monitoring.
- **Growing awareness and interest in Martha's Rule.** Organisations across England and internationally are expressing a desire to adopt the model and to explore how it can be extended beyond inpatient wards into maternity, emergency department and mental health settings.
- **Cross-cutting advocacy behaviour.** Many individuals are linked to or supported by campaign groups and MPs, showing increasing organisation and coordination in patient advocacy, rather than isolated complaints.

Building trust in AI in healthcare

Artificial intelligence (AI) has the potential to improve healthcare through supporting earlier diagnosis, more personalised care and reducing pressure on clinicians. Realising these benefits depends on ensuring AI is used safely, transparently and in ways that patients and professionals can trust.

With Prof Alastair Denniston, Chair of the AI Commission

The National Commission into the Regulation of AI in Healthcare was established to explore how this can be achieved. The AI Commission is an expert, non-statutory advisory body established by the MHRA to review current regulations and provide recommendations for a new regulatory framework for AI in healthcare, chaired by Professor Alastair Denniston.

As Deputy Chair of the AI Commission and Chair of the Health Systems Working Group, Prof Hughes has helped ensure that patient safety, public confidence and lived experience remain central to this work.

Putting patients and the public at the centre

The National Commission has placed patient and public voice at the centre of its work. This work has been supported by a wide-reaching programme of engagement. This included a call for evidence which received over 750 unique responses, polling of attitudes towards AI with over 12,000 members of the public and deliberative research with over 100 public participants.

Patients and the public have brought a perspective that no clinical trial or regulatory framework could ever fully capture.

Key insights include:

- People are generally supportive of AI in healthcare, particularly where it supports clinicians
- There is less comfort with AI making decisions independently, patients want a clinician involved in their care
- Transparency, fairness and clear evidence of safety are essential.

Patients and the public consistently emphasised the need for:

- Clear explanations of how AI is used in their care
- Assurance that systems are fair and work for all groups
- Evidence that AI improves outcomes, not just efficiency.

Supporting clinicians to use AI safely

Targeted engagement with healthcare professionals and healthcare leaders has been at the heart of this work. A clear message has emerged: AI can strengthen not replace, clinical judgement, but only when systems are well understood and trusted.

Current challenges include gaps in AI knowledge and confidence across the workforce, as well as the risks of both over-reliance on and underuse of emerging technologies.

Clinicians need the right training and support to use AI safely and confidently.

For safe adoption, clinicians need:

- Training to understand how AI tools work and their limitations
- Practical support to use them safely in real-world settings
- Confidence in the reliability of the systems they are using.

Clear accountability

What the Commission heard from clinicians is that clear responsibility for decisions, which lead to patient harm, is also essential. As AI becomes more integrated into decision-making, the Commission has explored who is accountable if something goes wrong, whether that is the clinician, the healthcare organisation or the technology developer. This will be important for protecting patients, supporting clinicians and maintaining public confidence.

Ensuring legal frameworks keep pace with innovation and continue to learn and adapt over time will help tackle uncertainty about responsibility, which is a key barrier to adoption.

A proportionate approach to regulation

The Commission's regulatory approach is structured around five key elements – Product, Producer, Provider, Professional and Proportionality in regulation. The 5 Pros approach provides a comprehensive framework for ensuring that innovation in AI is safe, fast and trusted.

This approach balances the need to adapt to rapidly evolving technologies with a continued focus on patient protection. It is underpinned by core principles of safety, transparency, fairness, accountability and the right to challenge decisions and seek redress.

As AI use continues to expand, it will be important that patients understand and are comfortable with, how tools are being used as part of their care. Regulation should consider how providers can demonstrate that they have adequately informed and supported patients to be aware of the use of AI in their healthcare, while remaining proportionate as public understanding and acceptance of AI grows.

Continuous safety monitoring

Safety does not stop at approval. AI systems operate in complex, changing environments and their performance can evolve over time. Continuous monitoring, robust testing and oversight are essential throughout their lifecycle to ensure they remain safe and effective.

The Commission has recognised the important role of patients and healthcare professionals in this process. They are often the first to recognise when outputs seem inaccurate, biased or inappropriate and their feedback helps identify and address issues quickly.

Creating an AI-ready health system

What the Commission heard consistently from patients, professionals, providers and industry is that AI has the potential to support safer, more effective care if introduced thoughtfully, monitored carefully and centred on patients at every stage.

Safe adoption depends not only on the technology, but on the system in which it operates. This includes strong digital infrastructure, clear governance and oversight and a workforce equipped with the right skills.

The Commission has explored ways to support organisations to assess their AI readiness and to strengthen safety monitoring across the system.

At the time of writing, the Research and Engagement report has been published, with the AI Commission's full report expected to follow in late summer 2026.

Further information can be found on the National Commission into the Regulation of AI in Healthcare website: **https://www.gov.uk/government/groups/national-commission-into-the-regulation-of-ai-in-healthcare**

Strategic priorities for 2026–27

The Patient Safety Commissioner will continue to act as an independent champion for patients, ensuring that their voices inform both current safety improvements and the safe adoption of future healthcare innovation through a system-wide collaborative and evidence-led approach.

Following the Dash Review in 2025, the Commissioner retained all her statutory powers, but her remit is now more clearly focused on improving patient safety and the value of listening to patients in relation to medicines and medical devices. In her second term the Commissioner will:

- Strengthen the use of the patient voice in national decision-making, ensuring that improving patient safety is a key system driver in relation to medicines and medical devices
- Use patient and system insights to identify and address priority risks associated with the safety of medicines and medical devices, including tackling inequalities
- Embed the Patient Safety Principles across policy and practice.

Finance

The Office of the Patient Safety Commissioner maintains clear lines of accountability for both its operational activities and financial management.

Operational accountability is to Parliament, while financial accountability and the effective stewardship of public funds for 2025–26 sit with DHSC.

In line with these arrangements, financial assurance processes including internal and external audits, were undertaken by DHSC, with further detail available through the Department's published accounts. The Office continued to utilise DHSC banking services to support day-to-day operations. The Commissioner's expenditure for the 2025–26 financial year is consolidated within the Department's annual report and accounts.

From 2026–27 day-to-day financial management of the PSC budget will be undertaken within the MHRA's financial systems and controls, with funding provided by DHSC.

Patient Safety Commissioner
Listening to Patients

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