Patient Safety
Commissioner
Listening to Patients

# PSC Impact

## The first three years of the Patient Safety Commissioner role

September 2025

# Introduction

Promoting the safety of medicines and medical devices and promoting the value of listening to patients and the public in regard to medicine and medical device safety seems so obviously right that it should be unnecessary. But listening to the experiences of patients and their families in the healthcare system, I can see that there is still a huge amount to do. This is not because anyone is setting out to harm patients, far from it, but the siloed, disjointed healthcare system described by Baroness Cumberlege in *First Do No Harm* still continues today.

There is an inherent epistemic injustice which silences the voices of patients, families and junior healthcare staff. To change this requires a shift in our mindset to work with patients as partners, to respect and value their voices and keep them safe. I have learned more from listening to patients in this role than in more than 30 years as a doctor. Patients and their families have given me hard truths about the language that health professionals use to protect ourselves such as discomfort rather than pain, such as infection rather than sepsis, and jargon rather than plain English. Patients and the public deserve better than this.

I see signs that changes are afoot. With the publication of the 10-Year Health Plan and its focus on the patient voice as central to designing and delivering healthcare, I feel optimistic that we have the necessary political clout. With the implementation of the Martha's Rule showing so quickly that listening to patients and families saves lives that it has been extended to all 210 acute inpatient sites in England. And with so many other initiatives that chip away at the fortress that is the NHS, to open people's minds to the value of listening to patients. As well as the moral argument that this improves safety, there is an economic and a productivity argument that being a sensing organisation that detects signals early and acts upon them can prevent harm, save money, and reduce length of stay.

It has long been established that healthcare staff can identify and escalate concerns using incident reports to make quick improvements to patient safety. What is less well known, or even believed, is that reports from patients and families have even more relevant information if used effectively. Whether this is described as patient stories, patient experience or patient safety data the outcome is the same - prevention of harm, better use of resources, and a safer healthcare system.

A lot has changed in the three years since I took up my post, with a public consultation that led to the Patient Safety Principles, options for redress for those harmed by healthcare set out in the Hughes Report, and a focus on the needs of patients with sensory impairments in The Safety Gap. I welcome the response from the healthcare system to these and other recommendations I have made. The MedTech strategy includes the new Medical Device Outcomes Registry, a key recommendation from *First Do No Harm*. I am delighted that the Patient Engagement Forum has been established to run alongside the MedTech strategy programme board. Bringing the voices of patients together with clinicians, commissioners, officials, industry and healthcare providers has got to be the way to get the best outcomes for all. I have seen substantial positive changes in the way that MHRA engages with patients and families, and I am looking forward to working even more closely with the regulator to continue our shared ambitions on patient safety and listening to patients. I have seen positive changes in the way that NHS Resolution approaches claims with a restorative rather than a confrontational approach and I welcome the planned overhaul by DHSC of the complaints process which requires substantial improvement, as witnessed by the number of complainants who approach the ombudsman.

Looking back to when I set out my initial and then revised strategy, I can see that we were ambitious with a small amount of resource but a huge amount of energy. The motivation comes from the experiences of families and their desire that others should not suffer the same losses or harm. Motivation also comes from the desire of healthcare workers and leaders to provide the very best care for their patients and from the tireless advocacy of those speaking up on behalf of patients, including members of both Houses of Parliament. In this short paper we have attempted to set out a summary of our work and to describe a new future in which patient partnership is normalised, where safety is designed in from the start, and where patients' outcomes and experience are the responsibility of all involved in the business of healthcare.

Henrietta

**Professor Henrietta Hughes OBE**
**Patient Safety Commissioner for England**

# Wide-ranging improvements in safety

The first Patient Safety Commissioner, Professor Henrietta Hughes, has driven wide-ranging improvements in patient safety, leading to lives saved and a reduction in patient harm from healthcare. Her work has led to many changes that will improve patient safety and the way that healthcare systems listen to patients.

The Cumberlege Review in 2020 recommended the appointment of a Patient Safety Commissioner who would be an independent public leader with statutory responsibility. The PSC would champion the value of listening to patients and promoting users' perspectives in seeking improvements to patient safety around the use of medicines and medical devices. The Commissioner would call the healthcare system to account by actively working in partnership with other organisations when this would deliver the most effective results.

Baroness Cumberlege envisioned the Patient Safety Commissioner as a 'golden thread' across a disjointed and siloed healthcare system, ensuring that patients' voices would be central to their care.

Professor Hughes took up her post in September 2022. In December of that year, she gave a speech at the Global State of Patient Safety meeting about her initial findings:

'I have discovered that we need a seismic shift in the way that patients' and families' voices are heard. This requires changes in legislation, regulation, policy, commissioning, education, professionalism, attitudes, behaviours, and culture. Everything we do as a healthcare system, because everything we do is about patients.

'In my hundred days report I will set out the immediate steps that need to be taken to ensure that patients' voices are at the top of the agenda. So that people get the information and data they need to make the right choices about their healthcare involving medicines and medical devices. That patients have the psychological safety to voice concerns knowing the right action will be taken. That the system truly responds swiftly, compassionately and in a joined-up way. I want us to be able to look back in astonishment on the way that we operate now.

'The healthcare system has always moved forward. This is the moment to set a new course, with shared decision-making and patient partnership as our destination. Without listening and acting on patient voices, safety continues to be compromised, and patients and families continue to suffer the consequences of harm.'

The PSC role represents a fundamental shift towards putting patient voices at the centre of healthcare decisions, for patients to be seen as partners in their own care, and for them to be included in the design and delivery of healthcare.

# Strategic impact

The PSC has impacted on a broad range of work across the healthcare landscape, including public inquiries, national reviews and organisational plans and strategies, incorporating the Patient Safety Principles, the strategic objectives set out by the PSC, and new ways of working in partnership with patients.

The Commissioner developed and promoted a new set of Patient Safety Principles published in 2024 and applicable to all those working in the healthcare system. The Patient Safety Principles are being incorporated into a wide range of different organisations' strategies including the GMC's corporate strategy and the core of the patient safety strategy of the independent Circle Health Group.

She contributed to public inquiries, including the Infected Blood Inquiry, the Covid Inquiry, the Thirlwall Inquiry, the Lampard Inquiry, and a range of national reviews, including the Leng review of physician associates and the review of the Alemi case, and several public consultations. Her input into the Infected Blood Inquiry resulted in a citation in the final report in which she is quoted: 'It is clear that the culture is getting worse and unless leaders set out a strategic intention to listen and act, we are heading straight back to the days of Mid Staffs and other health scandals, severe harm, and death.'

One of the strategic aims of the PSC is improvements in patient consent and the PSC helped develop the principles of consent, working with NHS England, NHS Resolution, professional regulators and the Patients Association to provide patients with a framework for ensuring they received information about the benefits, risks, alternatives and option of doing nothing (BRAN) before undergoing treatment. The PSC notes the inclusion of patient consent in relation to childhood vaccination and genomic medicine in the 10-Year Health Plan, and the PSC would welcome a broader focus on improved patient consent for all medicines and medical devices.

## *Restorative practice*

A strategic aim of the PSC is an overhaul of complaints and clinical negligence, promoting restorative practice to support patients, families and healthcare workers. These have been incorporated into the strategy of NHS Resolution and the aims of the 10-Year Health Plan. NHS Resolution succeeded in keeping a total of 83% of cases out of court by focusing specifically on a restorative practice approach as set out in the PSC's strategy. Its chief executive, Helen Vernon, said: 'At NHS Resolution, our 2025-28 corporate strategy *Resolution through collaboration* aligns closely with the Commissioner's vision of creating a culture of safety and being transparent.

'Our commitment to continuing our work to foster a just and learning culture where every patient's voice is heard and supporting NHS staff to deliver a compassionate and open response when something goes wrong, reflects the restorative practice approach that underpins effective patient safety. Rather than viewing incidents purely through a legal or financial lens, we recognise that learning from mistakes and sharing insights back to the NHS is fundamental to improve safety and manage risk.'

## *Complaints*

As the Commissioner, the PSC has received correspondence on a wide range of matters, including on harm from medicines and medical devices but also on concerns about access, quality of care, professional behaviours and attitudes, and other patient safety issues. Patients and the public are unclear who to approach in the healthcare system, whether the provider, the Commissioner, the CQC or professional regulators. Very often people have been bounced around the healthcare system as organisations give different and sometimes conflicting advice or because patients and families have not received the explanation that they are seeking. Whilst the Commissioner and her team engage with a large number of patient groups, it is not always possible to provide the level of engagement to meet the needs of all harmed by healthcare. The PSC has worked closely with a number of organisations to align information for patients and to ensure that the correct signposting is given. The ability to support all the patients who raise issues to the Commissioner is hampered by the constraints of the PSC remit and limited resources. Patients have also told the PSC that when they wished to give feedback to providers they were asked to write a complaint letter, but their feedback has not led to learning or improvement.

**The Patient Safety Principles have been incorporated by a wide range of organisations, from safer transfusion guidelines to healthcare providers, trade bodies, and professional regulators, impacting on the safety of patients in England and internationally**

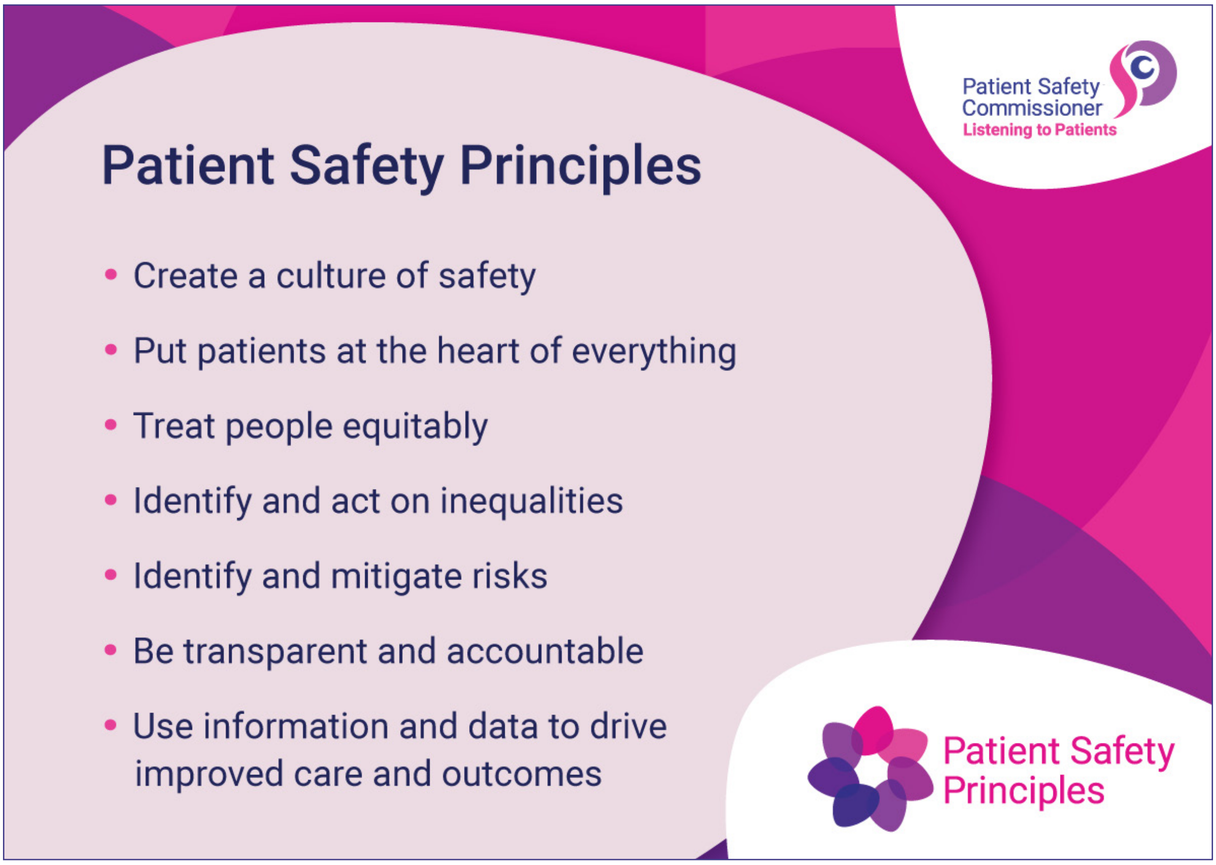
Due to the concerns raised by patients and families, the PSC wrote a joint letter with the former Parliamentary and Health Services Ombudsman to the DHSC Permanent Secretary calling for an overhaul of complaints.

The PSC's involvement in the development of the 10-Year Health Plan, published in July 2025, contributed to its focus on listening to the views of patients. This includes the establishment of a new Patient Engagement

Directorate within the DHSC to take responsibility for significantly improving the complaints function across the NHS, to seek to improve wider patient voice and engagement work, and to take responsibility for advocacy support for people wishing to complain.

# Policy

## *Principles*



Patient Safety Commissioner
Listening to Patients

**Patient Safety Principles**

- Create a culture of safety
- Put patients at the heart of everything
- Treat people equitably
- Identify and act on inequalities
- Identify and mitigate risks
- Be transparent and accountable
- Use information and data to drive improved care and outcomes

Patient Safety Principles

The PSC developed the first national Patient Safety Principles. The principles were shaped by key partner organisations, including the NHS Race & Health Observatory, the HSSIB, the CQC, the Patients Association, NHS Providers, and the GMC. Over 800 people submitted responses to the public consultation which directly informed the final version, published In October 2024.

Since publication, the PSC has conducted a wide-ranging engagement exercise to encourage organisations to embed the principles on an individual, team and organisational level. Key collaborations with the Department of Health and Social Care, the CQC, the Professional Standards Authority, the independent health sector, insurers and other organisations have been central to driving integration and fostering collective ownership of the principles.

To date, the Principles have been incorporated into the ABHI Code for clinicians and manufacturers, submitted for the consultation on the NHS Constitution, and embedded in the work of NHS and independent sector providers.

One of the leading independent healthcare providers, the Circle Health Group, based its Patient Safety Strategy 2025-2028 on the principles. The Circle Health Group patient safety strategy objectives take the wording of the Principles and integrate them into operational approaches with clear and practical goals. Through alignment and incorporation, the Principles can be used to set objectives and evaluate patient safety outcomes.

The PSC is in ongoing discussion with the CQC regarding potential opportunities to embed the Patient Safety Principles in its ongoing work on Quality Statements. Quality Statements are concise, outcome-focused declarations used by the Commission to set clear expectations for providers of health and social care services. Many of the new Quality Statements reflect the spirit and ethos of the Principles, for example learning culture, safe systems, pathways and transitions, equity in access and equity in experiences and outcomes.

The Principles have also shaped the Assisted Dying Bill, which is currently making its way through Parliament. At the request of the bill sponsor, Kim Leadbeater MP, the Patient Safety Commissioner conducted a principles-based analysis of the Bill. Using the Principles as an analytical lens, she aimed to evaluate how effectively the draft legislation and initial amendments met the goals of the Principles, particularly around transparency, patient centredness, and accountability. By incorporating the Principles into the bill, it is intended to embed patient voice into its workings, enhancing the safety and patient centredness of the final process.

The Patient Safety Principles closely align with those of the Community Pharmacy Patient Safety Group (CPPSG). Following the Human Medicine Regulations amendment in 2023, the CPPSG produced guidance and a risk assessment for use in the exceptional

> *‘The Patient Safety Commissioner role has continued to shine a light continuously on important issues throughout her first term. From the introduction of Martha’s Rule to the work on valproate and mesh, the role has had impact and made change.’*
>
> *Thea Stein, chief executive of the Nuffield Trust*

situations when valproate-containing medicines are supplied in different packaging from the original packs. The resources ensure the needs of each patient are taken into consideration when supplying valproate-containing medicines and support patients to manage their medicines safely. The resources have been requested and shared with many ICBs and peers across the system to enable them to review and adapt for use in different settings.

Between October 2024 and June 2025, the Patient Safety Commissioner has presented the Patient Safety Principles to 34 organisations, ranging from professional bodies, Royal Colleges and regulators to NHS organisations, at national conferences, industry forums and international networks.

These engagements are helping to embed the Patient Safety Principles across healthcare, and to ensure that they are followed by as wide a group of partners as possible.

The Commissioner has also engaged with the DHSC on the potential inclusion of the Principles within the forthcoming revision of the NHS Constitution. The NHS Constitution establishes the fundamental values, commitments, rights, and responsibilities guiding the provision of NHS services in England, and it is periodically revised to reflect evolving priorities and public expectations. By embedding the Principles into this document, there is an opportunity to reinforce the centrality of patient safety and patient voice as core commitments across all NHS services.

Embedding the principles in all these areas will ensure that they become a framework for decision-making that includes the patient's perspective, across the healthcare system.

## Medicines safety

The PSC receives correspondence from patients and their representatives as well as from healthcare staff around a wide range of issues related to the safety of medicines. Through regular engagement with the MHRA, the PSC has escalated these concerns, which has led to further investigation and expert assessment by the MHRA and the Commission on Human Medicines. Alerts have been issued on the safe use of isotretinoin, valproate and fluoroquinolones which have led to changes in NICE guidance and changes in clinical practice. The PSC has supported and encouraged the MHRA to further strengthen its work on engaging actively with patients, families and patient groups and listening to its views and experiences, to make improvements to the safety of medicines and medical devices. The following are a small sample of concerns about medicines that patients have raised to the PSC where actions have been taken as a result.

## *Valproate*

Valproate is a potent teratogen which can only be prescribed to women of childbearing potential if they are on the pregnancy prevention programme. This requires patients to receive safety warnings about the risk of valproate in pregnancy on packaging of medicines and patient information leaflets. Following information shared by a patient, who in September 2022 had been dispensed valproate in a plain white box without warning labels or a patient information leaflet, the PSC immediately raised concerns to the MHRA and to the General Pharmaceutical Council (GPhC). The following day the GPhC wrote to 91,000 pharmacists to remind them that valproate must be dispensed in accordance with the pregnancy prevention programme, including patient warning labels and information leaflets, and the PSC followed up with the superintendent pharmacists at two of the major high street pharmacy chains.

Learning that the results of a public consultation on original packaging had been delayed, the PSC spoke directly with the former Minister for Patient Safety in February 2023. Subsequently, steps were taken which ultimately amended the Human Medicines Regulations in October 2023 so that valproate could be safely dispensed in its original packaging with appropriate safety information about the risks of exposure to the foetus made available to patients.

**The PSC recommendation to monitor teratogen prescribing across the patient pathway reduces the risk of harm from foetal exposure to medicines**

The Cumberlege Report, *First Do No Harm*, described the healthcare system as siloed and disjointed and the PSC identified this in the patient pathway for women taking valproate. Valproate might be started in hospital, contraception managed in a community clinic, prescriptions issued by a GP, and dispensed by a pharmacist with no access to the full patient record. That fragmentation meant some women were inadvertently prescribed valproate during pregnancy. The Commissioner therefore made a recommendation to NHS England for 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, which was accepted in January 2024. In September 2024, NHS England reported that all ICSs had established this system initially for valproate and ensured that there is oversight of the whole patient pathway when the most potent teratogens are prescribed, keeping patients and their families safe. South East Clinical Quality Improvement team have also pioneered work in valproate safety, including patient information leaflets translated into 30 languages and EasyRead.

The Commissioner welcomes the improvement in safe prescribing of valproate and safety initiatives brought in by partner organisations, including NHS England and the MHRA. When the PSC started in post in 2022, three babies a month were born exposed to valproate. First quarter data shows:

- a 53% reduction in initiation in girls aged 0-12
- a 60% reduction in women aged 13-54 started on valproate
- a 65% reduction in women re-starting valproate after a break of 6 months
- at least 9 out of 17 mothers have active management of valproate if it was prescribed during a month when the woman was pregnant – this may include post-natal prescribing
- and hospital admissions for women with epilepsy aged 13-54 have not been affected by these changes.

Now, potentially hundreds of women - and their babies - have been spared that harm.

The PSC also worked with regulators such as the MHRA, the GMC and the GPhC to streamline information on their websites about highly effective contraception as part of the pregnancy prevention programme for patients and worked with teams at NHS England and the Faculty of Sexual and Reproductive Health in this area.

The Commissioner has worked with commissioners and researchers who have set up the Fetal Exposure to Medicines Service, shared between Manchester and Newcastle NHS trusts, to support families in the North of England whose children have been exposed to valproate in utero. The service has seen 44 families to date, ensuring that patients exposed to valproate in utero receive the right diagnoses and correct treatment. It has been commissioned to see 100 families and has already identified valproate harm in previously undiagnosed siblings. It is vital that this service is extended to cover patients across the whole of England to ensure that individuals who have been harmed get access to relevant treatment and support.

The findings from the Hughes Report have been shared with researchers across the world, with clinicians from Norway, New Zealand and the US keen to ensure that similar processes are put in place for their patients.

## *Fluoroquinolone*

Fluoroquinolones are a class of antibiotics used to treat infections such as kidney and prostate infections. However, they are known to have rare but catastrophic side effects which are not possible to predict. Patients and family members raised concerns with the PSC in September 2022 that they had experienced side effects but had not been informed this was a possibility when their treatment was prescribed. The PSC raised these with the MHRA and the Commission on Human Medicines reviewed the evidence.

The MHRA published a drug safety update which was updated in January 2024 and NICE updated guidance on prescribing of fluoroquinolones. The Commissioner then worked with Royal Colleges to ensure this updated guidance leads to changes in clinical practice so that patients are only prescribed fluoroquinolones in line with NICE guidance.

## *Isotretinoin*

After a meeting in October 2022 with families of young people who had taken isotretinoin (Roaccutane), a medication to treat acne, and who had taken their own lives or suffered severe sexual side effects, the PSC raised their concerns with the MHRA. The Agency engaged with family members as stakeholders, setting up focus groups to hear directly from those affected. Following expert advice from the CHM, the MHRA issued a safety alert for isotretinoin in October 2023 to strengthen the safe use of isotretinoin, including additional oversight of the initiation of treatment for patients under 18 years of age and through improved assessment and monitoring of mental health and sexual function issues.

## *Antidepressant deprescribing*

In 2022-23, 8.6 million adults in England were prescribed antidepressants, which includes SSRIs and other types. The PSC was contacted by patient groups highlighting the problems some patients

*'The Patient Safety Commissioner has worked with Sling the Mesh in a number of ways, including supporting our call for financial redress for women harmed by all types of pelvic mesh looked at by the IMMDS review, including rectopexy mesh. She has also supported our work on the implementation of recommendation 8b of the IMMDS review, which calls for mandatory, statutory reporting to a central register for pharmaceutical and medical device industries of payments made to the healthcare sector. In addition, she worked with us on the development of a resource for patients to help GPs identify the complications of pelvic mesh.'*

*Kath Sansom, founder of Sling the Mesh campaign group* experience when trying to safely stop taking antidepressants, as withdrawal symptoms can mirror symptoms of anxiety.

The Commissioner convened a meeting between NHS England, the Royal College of General Practitioners and the Royal College of Psychiatrists, who agreed a joint aim to support safe deprescribing of antidepressants by co-producing a resource for GPs on excellence in starting, monitoring, and safe deprescribing of antidepressants which is in progress.

The Commissioner has supported the NHS England medicines optimisation opportunity, addressing inappropriate antidepressant prescribing, for which 11 of the 42 ICBs have signed up.

The PSC made a request for pilot funding to support safe deprescribing of antidepressants to the Secretary of State and the group is awaiting a response.

The PSC actively supported the Beyond Pills movement throughout the year. The associated All-Party Parliamentary Group strives to move UK healthcare beyond an overreliance on pills by combining social prescribing, lifestyle medicine, psychosocial interventions and safe deprescribing to improve outcomes and reduce health inequalities.

Health Minister Stephen Kinnock responded to a written PQ on 31 March 2025: ‘To ensure antidepressant drugs are made available to patients only where the benefits outweigh the potential harms, NHS England is encouraging the integrated care boards to address inappropriate antidepressant prescribing and to consider commissioning services for patients wishing to reduce or stop using antidepressants.’

### *Clozapine*

Concerns about the safe prescribing of Clozapine, an antipsychotic, were raised by patients’ families with the PSC and she escalated concerns about the monitoring of this medication in February 2024. The PSC has concerns about Clozapine being prescribed in settings where the relevant expertise about monitoring, or access to swift results of clozapine levels, may not be available. Moreover, she believes it is vital that patients and their carers are aware of the risks of Clozapine toxicity and that regular monitoring is needed.

She pointed to the fact that effective monitoring of this medication was as important as the safety of the medication itself and raised this with the MHRA and the Royal College of Psychiatrists, which set out a joined-up approach.

Health minister Karin Smyth responded to a PQ: ‘As Clozapine is used when other treatments have failed to manage a patient’s condition, careful monitoring is required to minimise the risks to ensure patients are able to receive effective treatment with Clozapine.’

The MHRA plans to seek views from patients, patients' families and healthcare professionals on methods to improve awareness of the risks associated with Clozapine and how to manage them.

## Medical device safety

### *MedTech*

The PSC regularly raises concerns about the safety of medical devices to relevant bodies including the MHRA. As well as flagging concerns after incidents, the PSC believes that we can keep patients safer by incorporating their views and experiences before, during and after care. The development of the Medical Devices Outcomes Registry is key to this, with new Patient Reported Outcomes and Experiences Measures (PROMs and PREMs) planned to run alongside it. The PSC has called for initiatives such as Scan4Safety, improvements in patient consent and better transparency and accountability to improve patient safety. As an independent advisor to the MedTech programme board, the PSC has sought to ensure that the views and voices of patients are included at every stage.

**The Medical Devices Outcomes Registry now contains data on 1.8 million implantable devices, making it easier to recall patients and reduce future harm**

The PSC was instrumental in the development of the DHSC's Quarterly MedTech Patient Engagement Forum which runs alongside the MedTech strategy. The forum provides a route in for patient groups to directly influence and co-design development of policy initiatives. Impact is reflected in the inclusion of patient-specific questions in the new value-based procurement standard guidance, due to be launched early next year, and involvement in the development stage for innovation passports referenced in the 10-Year Health Plan.

In her advisory role to check the MedTech programme board, the PSC has supported DHSC colleagues to identify any gaps in patient group stakeholder membership, identifying under-represented patient groups, which has contributed to the increased reach of the Forum. For example, making introductions to the Royal College of Obstetricians and Gynaecologists, to ensure improved coverage for women's health groups. The PSC also introduced representatives from the RNIB and the RNID to the group to give people with sensory impairment direct access to its work. The Forum now regularly invites over 70 individuals from 45 patient groups. Attendance at the quarterly Forum meetings doubled between March 2024 and January 2025.

The PSC's work with the MedTech Patient Engagement Forum also ensured that equity and the views of patients and the public are included in all aspects of medical devices use, including the design, procurement, and responding to patient safety concerns. An example of this was that, following the NHS Race & Health Observatory World Cafe conversation, the PSC committed to highlighting racial bias in medical devices, such as pulse oximeters and bilirubinometers, and highlighted these examples to the MedTech programme board.

As part of the MedTech Programme, NHS England's Outcomes and Registries Programme received Directions from the Secretary of State in March 2024 to allow it to collect data from NHS and private healthcare providers to fulfil Recommendation 7 of the Independent Medicines and Medical Device Safety Review (2020) and Recommendation 1 of the Paterson Inquiry (2020). Since then, the Programme has implemented a Medical Devices Outcomes Registry (MDOR) to collect data on procedures involving high-risk implantable devices. It is clinically led and guided by wider stakeholders including patient representatives.

The MDOR has initially prioritised the collection of device data from high-volume clinical specialities. At the end of May 2025, the MDOR contained data pertaining to 1.8 million implantable devices. The Programme will continue to implement and incorporate registries of other speciality areas, increasing patient coverage in pursuit of reducing variation in clinical practice, and monitoring and improving the safety and outcomes of patients. The PSC has supported the work of the MDOR team, ensuring that patient representation is present and that patient voice, in the form of PROMs and PREMs, is developed. This has included visiting NHS and independent providers, meeting with individual device registries and their patient representatives, promoting the involvement of patients, including those who have experienced harm from medical devices, and working with NHS trusts and suppliers of barcode technology to promote the Scan4Safety initiative.

## The Hughes Report

Following on from the recommendations made in the Cumberledge review *First Do No Harm*, about redress for those who have been harmed by primodos, valproate and pelvic mesh, the PSC raised this with the relevant minister. In 2023, she was asked to review the issue and provide advice on options for redress to the government for those harmed by valproate and pelvic mesh. In addition to this, the PSC published the Hughes Report in February 2024, a more detailed account of the impact of harm on patients and families. The Hughes Report also sets out a blueprint for a redress scheme for patients harmed by medicines and medical devices.

The report makes 10 recommendations to government on how to provide redress to those harmed, including the need for the government to provide comprehensive financial and non-financial redress.

The report made a number of recommendations:

- 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.
- 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.
- The government should create a two-stage financial redress scheme comprising an Interim Scheme and a Main Scheme.
- The Interim Scheme should award directly harmed patients a fixed sum by way of financial redress. These payments should start during 2025.
- 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.
- Patients who received relevant treatment through either the NHS or independent sector should be eligible for the Interim Scheme and Main Scheme.
- 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. Which should make the process better.

**There have been 43 Parliamentary Questions on the Hughes Report, valproate, or mesh – 18 questions focussed on the Hughes Report itself, 28 questions were on issues about valproate and 14 related to mesh harm**

- Both the Interim Scheme and the Main Scheme should be administered by an independent body which commands the confidence of patients.
- Both the Interim Scheme and the Main Scheme should effectively signpost harmed patients to services which can provide them with free emotional support.
- 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.

Since publication, members of both Houses of Parliament have maintained a consistent pressure on the government for action. The bulk of scrutiny centres on the two core areas singled out in the report – timely redress for families affected by valproate and for women injured by pelvic mesh. Questions on the report itself focus on when ministers will confirm a timetable, how the scheme will be funded, and how devolved administrations will be involved.

There have been 43 Parliamentary Questions relating to the Hughes Report, valproate, or mesh. Of these, 18 questions have focussed on the Hughes Report itself, in terms of progress, government response or funding. Twenty-eight questions raised issues about valproate, such as compensation, interim payments or wider support. There have been 14 questions which have related to mesh. Furthermore, in Parliamentary debates, there have been two questions to Ministers which have addressed the timeline of the Hughes Report. Prime Ministers of both the current and the previous governments have answered questions about timelines at Prime Minister’s Questions and in their answers, both have made commitments to provide a response to the Hughes Report.

In March 2025, a Westminster Hall debate was held in Parliament shortly after the first anniversary of the publication of the Hughes Report, during which MPs repeated calls for a government response to the report’s recommendations and a government minister provided a fulsome apology to patients and families who had been harmed by these interventions.

The PSC is still awaiting a full government response to the recommendations contained in the Hughes Report for financial and non-financial redress.

Meanwhile, following the recommendation for non-financial redress, the DWP has begun looking at how harmed patients can avoid repeated assessments to access benefits and, whilst the PSC welcomes the Fetal Exposure to Medicines Service (FEMS) pilot which has been established for patients in the North of England, it is vital that all children exposed to valproate in utero are able to access this specialist diagnostic and treatment service wherever they are in the country.

# The Safety Gap

Following concerns raised by patients with sensory impairments about the safety and accessibility of medicines, the PSC identified that patients with sensory impairments were not routinely included in health inequalities work programmes. From her own experience as a GP, the PSC was aware that patients with visual or hearing impairment often faced additional challenges with their healthcare and was determined to improve their situation in regard to the safety and accessibility of medicines and medical devices. Around 18 million adults have hearing loss, deafness or tinnitus in the UK and over 2 million people are living with sight loss. With the shift from analogue to digital in the 10-Year Health Plan there are great opportunities to improve accessibility for patients, if their voices are heard at all stages of the design and implementation of technologies, but risks if patients are left out of these discussions.

Because patients with diabetes are at greater risk of sight loss and also use medicines and medical devices on a regular basis, a 'deep dive' was conducted into the intersection of diabetes and sight loss, to draw on these patients' experiences for wider learning and improvement. In 2024 the PSC commissioned an academic researcher to examine the barriers to patient safety and accessibility for those with sensory impairment. Prof Mags Watson from the University of Strathclyde found a wide range of challenges, specifically for those with sensory impairment and diabetes. The final report made four recommendations:

- The MHRA needs to review, working alongside patients, whether their current guidance and regulations for the licencing and packaging of medicines goes as far as is possible to enable their safe use by those with sensory impairment.
- The ABPI, the MHRA and DHSC should work together to restart work, alongside published milestones, to digitise paper-based patient information leaflets via the existing UK Electronic Patient Information (ePI)

*'The Patient Safety Commissioner has been a force for good in the health system since her appointment in 2022. She has become a trusted independent voice and a tremendous advocate for patients, with great convening power and providing a beacon for patient safety when the public feel that they have not been heard. We already collaborate on public and patient safety matters for medicines and medical devices, and I am delighted that we will soon be hosting the PSC and her team at the MHRA. We continue to champion patient safety, and I look forward to extending our close working relationship with the PSC as an independent advocate for patients.'*

*Lawrence Tallon*
*Chief Executive, Medicines and Healthcare products Regulatory Agency (MHRA)*

- Task Force. As part of this restart, the ePI Task Force should examine how to maximise the benefits of this work for patients with sensory impairment.
- NHS England’s Diabetes Programme Team should launch a patient reference group to assess, understand and mitigate the barriers and enablers to the safe and effective roll-out of medical devices and other education programmes for the management of diabetes (such as DAFNE) for those with sensory impairments.
- DHSC and NHS England need to ensure the work announced to improve and expand the NHS App in ‘Reforming elective care for patients’ includes an assessment, conducted with the input of patients, to determine whether further accessibility improvements are required, especially for people with visual impairment.

Following on from these recommendations, the PSC has received swift feedback from NHS England and the MHRA which is welcomed. The MHRA has confirmed it has restarted the work on ePI and will be engaging with patient groups with sensory impairments on this and also in understanding the needs of patients in terms of packaging and licensing of medicines. NHS England has welcomed the opportunity to engage with a wider group of patient representatives with sensory impairment on the development of the NHS App, so that this is inclusive and accessible to patients with vision and hearing loss.

## Martha’s Rule

Martha’s Rule has already had a substantial impact on patient safety and on the culture of working in partnership with patients and families, with many lives saved and a reduction of harm to patients.

In her second year, the PSC was invited by the former Secretary of State for Health and Social Care to develop the policy for Martha’s Rule. Martha’s Rule enables acute and specialist trust inpatients and their families to raise concerns about deterioration directly to Critical Care Outreach teams. It was developed following the tragic outcome of Martha Mills, who died of sepsis aged 13 after her and her family’s concerns were not escalated as needed.

After the success of the initial pilot, is now in operation in all acute trusts. Between September 2024 and June 2025, 4,906 calls were made to Martha’s Rule helplines to escalate concerns about care, leading to 241 potentially life-saving interventions being triggered, and there is international interest in introducing Martha’s Rule.

The PSC initially led the policy sprints that brought together system representatives to develop the policy in four weeks and her recommendations to the former Secretary of State were all accepted. Following this, she was appointed by the former Health

Secretary as the independent Chair of the Martha’s Rule Oversight Group and convened monthly meetings with Martha’s family, regulators, professional bodies and the DHSC to oversee the systemwide changes needed to make Martha’s Rule a success in England. This included the NHS England pilot, the joint statement from the CQC, the GMC and the NMC, advice given to legal panels by NHS Resolution and hearing from patients, professionals and representatives over the course of the year. In addition to this convening role, the PSC set out a programme of communications and engagement by visiting pilot sites and meeting staff and patients, speaking to professional and representative bodies, patient groups, professional regulators at global meetings and via national media to describe the whole system approach to working in partnership to gather feedback to refine and improve the process. In addition to all acute NHS inpatient hospital sites, several independent providers have introduced patient activated rapid response systems, and two medical schools have included it in their undergraduate training.

The latest published data covering the first six months of the NHS England Martha’s Rule pilot shows that between September 2024 and June 2025, 241 potentially life-saving interventions were triggered.

The new data published by the NHS shows almost three quarters (71.9%) of calls have been from families seeking help, with 720 calls leading to changes in care. This could include patients receiving a new medication such as an antibiotic.

Almost 800 (794) calls led to clinical concerns such as medication or investigation delays being addressed. A further 1,030 calls helped to resolve communication and discharge planning issues.

Professor Meghana Pandit, NHS national medical director, said: ‘There is no shadow of a doubt that Martha’s Rule is having a transformative impact on the way hospitals are able to work with patients and families to address deterioration or concerns about care.’

**241 potentially life-saving interventions were triggered as a result of Martha’s Rule between September 2024 and June 2025**

*‘When you are a victim of patient safety failures, it is common to be asked to talk at conferences. Much of the time you get the sense that nothing happens – you tell your sad story and very little changes. But my encounter with Henrietta at the Patient Safety Summit was different. Once she heard about the idea for Martha’s Rule, she took the idea to the then health secretary. It meant that when my interview with the BBC Today programme was aired in September 2023, it was met with an instant positive political response. Henrietta was also adept at talking to numerous stakeholders and keeping all parties ‘onside’. We have been grateful to have her independence, organisation and agility as well as the support she has given us as we’ve worked to make Martha’s Rule a reality for NHS patients today.’*

*Merope Mills, campaigner for Martha’s Rule*

‘There have now been almost 5,000 calls made to the hotlines, with hundreds of potentially life-saving interventions triggered, which is why we are now expanding Martha’s Rule to all acute hospitals in England.’

## Convening, engagement and communications

The Patient Safety Commissioner works across a broad landscape of healthcare and other organisations who have roles in patient safety and in listening to patients and the public in relation to medicines and medical devices.

Through horizon scanning, the PSC is able to work with others to identify and monitor any potential problems and to try and resolve these early on. The PSC works with the healthcare system where there are areas of concern related to the use of medicines and devices on outcomes required for change and the monitoring of these.

The Commissioner convenes groups of patients with the relevant part(s) of the healthcare system who are able to effect change and improvement. For example, the Commissioner convened meetings with the Campaign against Painful Hysteroscopy patient group, along with NHS England, GIRFT and the Royal College of Obstetricians and Gynaecologists, to understand what changes were needed to address painful outpatient gynaecological procedures. By listening to the patients’ concerns, changes have been made. Following on from this, RCOG updated its Green Top Guidance on Outpatient Hysteroscopy and steps have been taken to widen the availability of options for improved pain relief in outpatient hysteroscopy settings.

The Martha’s Rule Policy Sprints and Oversight Group meetings enabled the PSC to convene the family, patient representatives and the wider healthcare system to identify the factors that would make Martha’s Rule a success. By listening to a wide range of views and experiences and drawing on these, it was possible to develop the Martha’s Rule policy in a very short space of time, enabling the NHS England pilot to start rapidly and be continuously refined and improved, saving lives as a result.

The PSC has engaged with thousands of staff in the health system on her vision of an improved patient safety system and her strategies. She has also had regular meetings with key stakeholders in a wide range of organisations, including government departments, members of both Houses of Parliament, APPGs, select committees, manufacturers and trade bodies, healthcare regulators and arms-length bodies, providers, professionals, patient groups, charities, representatives, academics, Royal Colleges and associations and international groups. The PSC has worked to ensure that all groups were included in communications and engagement activities.

As well as visits to NHS trusts and independent sector organisations in England, she has engaged with partners in Scotland, Wales, Northern Ireland, Morocco, New Zealand, the Netherlands, the US and Australia.

She has been a regular voice on national media, presenting her views on the need to listen to patients to keep them safe. She has been a regular commentator on the development of policy for, and the impact of, Martha's Rule in working in partnership with patients.

Additionally, both the Hughes Report into redress options for those harmed by valproate and pelvic mesh, and The Safety Gap report on safety and accessibility of medicines and medical devices for people with sensory impairment, gained significant levels of media coverage including:

- over 20 pieces of national print and broadcast for the Hughes Report
- a total of 170 articles in national and local media and a combined reach of 512,138,444 for The Safety Gap report.

The PSC also delivered many keynote presentations at major high-level conferences, including at the WHO, the Global Ministerial Health Summits in Santiago, Chile and in Manila, Philippines, at the Patient Safety Movement Foundation, the IHI/BMJ International Forum and the Health Equity Action Lounge @ Davos during the World Economic Forum 2025.

The media coverage and presentations enabled the PSC to share her key messages with both the public and the wider healthcare landscape.

## *Patient information*

The Commissioner ensured that the A-Z of medicines was added to the NHS App in 2024 and recommended restarting the Electronic Patient Information (ePI) Task Force to enable all patients to get the information they need about their medicines in the most accessible way.

The Commissioner has also included links to relevant organisations on her independent website and published examples of good practice in the form of blogs.

*'Since the role of the Patient Safety Commissioner was established, there has been a welcome focus on strengthening the patient voice in matters of safety and transparency. At the ABPI, we have valued the Commissioner's constructive challenge and her emphasis on practical improvements, notably the need for better access to electronic patient information (ePIL), as highlighted in The Safety Gap report. The Commissioner has also engaged thoughtfully on the topic of industry disclosure in a way that has supported progress. Even without legislation, the industry's commitment to transparency has grown year on year, reflecting shared goals around patient trust.'*

*Amit Aggarwal,*
*Executive Director Medical Affairs and Strategic Partnerships, the Association of the British Pharmaceutical Industry*

# Leadership

Over the past three years the PSC has been a baton carrier for leadership of and accountability for patient safety in the healthcare system.

She co-founded the Patient Safety Leaders Informal Network and assumed the chair along with the national patient safety director. She also set up the Conversations about Safety informal network, which provides a safe space for NHS and independent sector executives to meet and discuss patient safety matters involving medicines and medical devices.

The Patient Safety Commissioner believes that leaders play a vital role in establishing a safety culture which puts patients first. She has promoted the need for senior leaders to be leaders in patient safety and worked with NHS Providers to help them establish stand-alone training for NHS Trust Board members.

From her conversations with NHS trust executives, the PSC learned that the NHS England planning guidance made no reference to patient safety and that trust leaders wanted to see patient safety embedded in the planning guidance. Following a letter from the PSC to the CEO of NHS England, patient safety was included in the 2024 planning guidance for the NHS for the first time. The Commissioner also highlighted language blaming patients in the NHS specialised commissioning national specification which was then changed to more inclusive language. The Commissioner encouraged NHS England to involve patients in the drafting of their documents to avoid repetition. The Commissioner encouraged NHS England to include evidence directly from patients at their main board meetings, as well as at their Quality and Safety Committee, and for the NHS England Board to receive training on patient safety, which was carried out.

The PSC asked the HSJ Patient Safety Congress to include a leadership strand at its annual event so that leaders remained engaged in, and accountable for, the safety of their patients. This was launched at the 2023 HSJ Patient Safety Congress and has continued annually, with the PSC speaking at well-attended sessions for senior leaders at the event.

The PSC identified that the induction programme for trust non-executive directors lacked any information about patient safety. Following a request from the PSC, NHS Providers has developed specific training on patient safety for trust senior leaders. The PSC has also met with CQC inspectors to promote patient safety and the value of listening to patients in relation to medicines and medical devices.

## *Global reach*

As the first patient safety commissioner in the world, the PSC has also had huge international impact, helping to draft the WHO's Patient Safety Rights Charter, chairing a session at the WHO Patient Safety event on patient safety as a human right, providing evidence to the Scottish Parliament on the development of the Scottish PSC role and participating in global patient safety initiatives. The PSC is delighted that the Scottish PSC has now taken up her post and looks forward to working closely on patient safety improvements.

She has also engaged directly with patient groups in the US, New Zealand and the Philippines.

## Research, guidance and resources

The Commissioner is a member of the Advisory Board for the SafetyNet network of the six NIHR Patient Safety Research Collaboratives. With the SafetyNet network, the Commissioner helped to identify areas of potential research by a comparator of her strategy with their current research programme. The Commissioner has created an infographic on the value of listening to patient feedback via Care Opinion, based on SafetyNet research, and has shared this widely in presentations in England and internationally.

### *Guidance*

Following concerns raised by the Campaign against Painful Hysteroscopy, the PSC convened a meeting between the campaign group, the Royal College of Obstetricians and Gynaecologists (RCOG) and the NHS England GIRFT programme. The PSC has also brought the campaign group together with the Women's Health team at NHS England. Following these meetings, the RCOG have updated their 'Green Top' guideline 59 on outpatient hysteroscopy to ensure that women receive the right information to consent to treatment, including on minimising pain and optimising the experience of the woman.

The PSC has worked with ABHI on developing their Code Compass, which sets out the obligations of healthcare professionals, healthcare organisations and industry partners. By incorporating the Patient Safety

> *'We are deeply grateful for the Patient Safety Commissioner's support of our campaign. Since taking up her post, she has actively listened to families affected by the sodium valproate scandal and shown real empathy and understanding. Her endorsement of the Cumberlege Review and backing of our call for compensation has been invaluable. The Hughes Report reflects the very issues INFACT has campaigned on for years, and we were pleased to see our concerns fully recognised. However, we are deeply disappointed that the Government has yet to respond. Families deserve action, not silence, after decades of harm and heartbreak.'*
>
> *Emma Murphy and Janet Williams, INFACT (Independent Fetal Anti Convulsant Trust)*

Principles, the code empowers these groups to act and make decisions that improve patient outcomes and foster innovation in their field. The Code Compass helps healthcare practitioners and organisations uphold the highest standards of ethical practice, ensuring that patient well-being remains at the centre of care delivery. By focusing on principles such as patient-centred care, collaboration, and innovation, the code ensures that every stakeholder, patients, healthcare professionals, organisations, and industry, benefits from a shared commitment to ethical excellence.

The PSC has worked with the Serious Hazards of Transfusion (SHOT) team on the necessity of Positive Patient Identification and the Patient Safety Principles have also been incorporated into the SHOT Transfusion Safety Standards.

## *Resources*

The PSC received concerns from the campaign group Sling the Mesh that patients attending their GPs were not receiving the right information about mesh harm or options for onward referral. Working collaboratively with patient groups and health professionals, the PSC co-produced a resource for patients who had been harmed by pelvic mesh to take to their GP appointments. The aim of the resource was to raise GP awareness of potential mesh harm and to provide information on relevant investigations and referral routes to specialist mesh centres set up following *First Do No Harm*. This resource was circulated to the Sling the Mesh network of over 10,000 members.

The PSC also developed resources to support implementation of the Patient Safety Principles, including an A3 poster, a detailed background to each principle, and a guide to implementing the Patient Safety Principles as an individual for revalidation, as a team and at organisational level.

*'The appointment of Henrietta Hughes as the first Patient Safety Commissioner has led to a real shift in providing patients and their families with not just a spokesperson to act on their behalf but a real change agent in delivering the improvements needed to improve the safety of our patients. The incredible impact of her role has now been recognised and celebrated by many organisations and systems on a global scale and particularly through her influence at the World Health Organisation, the global not-for-profit Patient Safety Movement Foundation, and at the most recent Global Ministerial Summits on Patient Safety. As a result of the impact of the PSC within the NHS in England, the role and function are now due to be emulated by many other countries and systems across the world.'*

*Professor Mike Durkin OBE*
*Senior Advisor, Patient Safety Policy and Leadership*
*Institute of Global Health Innovation, Imperial College London*

# A view of the future

It has been a huge privilege to serve as the first Patient Safety Commissioner in the world. Anyone who has listened to patients or families harmed by healthcare will want to do everything they can to help them heal and to avoid a repetition for others. Whilst setting up the Patient Safety Commissioner function was a daunting prospect, the support and encouragement I received, despite all the barriers and challenges placed in my path, have reminded me that there are millions of allies who want to see the right outcomes for patients. The public, including current, past and future patients, want to know that everything has been done to keep them and their loved ones safe. Healthcare professionals want to work in a healthcare system that supports them to do the right thing for their patients and know that their voices will be heard if they raise patient safety concerns.

Healthcare leaders have opened their minds to new possibilities and showed a willingness to listen to patients and families in a better way, and lives have been saved as a result. The cultural barriers to listening to patients are not unique in the NHS or to England. By engaging with patient groups and their representatives from across the world I have heard strikingly similar accounts from highly developed healthcare systems and those in low- and middle-income countries where patients were not listened to and were harmed by healthcare. By showing that it is possible to have a government-appointed independent role to amplify the voices of patients into the heart of government and see changes happen, I hope that other countries feel inspired to know that there is a way to hear patients' voices and keep their citizens safe in their healthcare systems.

There is still, however, a huge amount to do and the publication of the 10-Year Health Plan and the Dash Review set out a new and exciting future which put patients where they should be, at the heart of everything we do in healthcare. The Dash Review recommends moving the hosting arrangements of the Patient Safety Commissioner to the MHRA, where the safety of medicines and medical devices and listening to the views of patients and the public around these logically sits. I am pleased that the independence of the Patient Safety Commissioner is not being compromised and that the role will still be able to amplify patients' voices and speak truth to power.

With the announcement of the new National Director of Patient Experience there are huge opportunities for turbocharging the way that the healthcare system values and responds to feedback from patients and their families, in whatever type of format that is given. This will be led from the Department of Health and Social Care, through commissioners to the frontline. Patients and their representatives will be looking intently at how a government department will stay connected to the real experiences of patients and avoid the groupthink that has led to historic injustices such as the Infected Blood scandal or the Post Office Horizon scandal.

While looking forward, we also need to look back at the harms that a disjointed and unresponsive healthcare system has caused to patients and families. Whilst I welcome the Fetal Exposure to Medicines Service and the steps that DWP are taking to consider the frequency of assessments, patients are still waiting for a substantive government response to the recommendations set out in the Hughes Report on financial and non-financial redress. A swift response would be a good first step to rebuild trust as an example of how the government can make good on its commitment to keeping patients safe and listening to their needs.

I believe that successful delivery of the 10-Year Health Plan needs to follow the steps outlined in the Patient Safety Principles we published in October last year.

The principles set out that we must create a culture of safety where patients are at the heart of everything we do. Where we treat people equitably and identify and act on health inequalities. Where risks are identified and mitigated, we are transparent and accountable, and we use information and data to drive improved care and outcomes.

When we published the Patient Safety Principles we were told that they were so simple and so obvious. To which I would suggest that if these were followed all the time and every day, the health care system would feel very different and patient harm and the culture of cover-up would be reduced. As Patient Safety Commissioner I work across a wide range of healthcare organisations and I have been fascinated by which parts of the system have stepped forward to incorporate the Patient Safety Principles as a way to improve their work, from the ethical standards in the ABHI Code Compass to the serious hazards of transfusion (SHOT) guidance, the Assisted Dying Bill amendments, and the strategies of professional regulators. Whilst some NHS trusts have adopted the principles, the uptake in the NHS has been slower than in the independent healthcare sector. This tells me something about the culture of the NHS and the permission-based system that many people feel they are working under. I hope that the Patient Safety Principles are included in the consultation on the NHS Constitution so they can become enshrined into the business as usual of NHS healthcare.

The future Patient Safety Commissioner strategy must incorporate the Patient Safety Principles and the three shifts in the 10-Year Health Plan, working closely with the MHRA, the DHSC and to ensure that the patient voice is represented on the revamped National Quality Board. The three shifts in the 10-Year Health Plan, from hospitals to community, from analogue to digital and from sickness to prevention, all require changes in the culture of the healthcare system which must be delivered with patients as part of these conversations.

First, hospitals to community. The red tape challenge has set the goal of standardised information flows between different parts of the healthcare system, including discharge summaries and clinic letters from secondary care into the GP system. I believe that this would enhance transparency and accountability, ensuring that information about medicines and medical devices is held by GPs. It would also remove some of the epistemic injustice that currently exists in the health care system, that is the injustice of language, of status and of knowledge. Structured medication reviews will help to identify risks of polypharmacy and ensure that patients understand their medicines, know how to use them, and are supported to do so.

Second, analogue to digital, the single patient record so that patients have information about their own care and those who are looking after them can have the full context when planning or delivering care. Information is power and empowering patients, carers and families to be partners in their care and part of the clinical team has got to be the way forward. The use of the NHS App as the front door of the NHS is so welcome, and I am encouraged by the inclusive approach of the team leading this work so that all patients benefit from this technology.

Third, sickness to prevention. A coordinated system approach to preventing harms from medicines and medical devices, reporting to the National Quality Board. This includes the areas of a safety management system, consent, transparency, Yellow Card reporting, audit and the Medical Devices Outcomes Registry as part of the MedTech strategy. There are 237 million medication errors each year in the NHS, costing £2.2bn and leading to 180,000 excess bed days, patient harm and deaths. We need a coordinated approach to reducing harm across the patient pathway into adult social care, through excellence in prescribing, dispensing, administering, monitoring and stopping medications. As we look ahead, the landscape of healthcare is changing faster than ever and with it, the opportunities and risks for patient safety.

Artificial Intelligence in healthcare holds extraordinary promise:

- AI-driven diagnostics and predictive analytics
- Personalised treatment plans
- Decision support and clinical records
- Enhanced patient safety and experience.

But with that promise comes responsibility. We must ensure AI systems are safe, transparent, and accountable – that their decisions can be explained, that they are free from bias, and that they are tested in real-world conditions with patients involved at every stage in the process, including reporting potential harms. Incorporating the Patient Safety Principles will ensure that safety is there from the start and no patients are left behind.

Beyond AI, there are innovations already in the NHS that, if spread and adopted at scale, could be transformational. Innovations which are embedded in some but not all NHS trusts, such as Scan4Safety, using GS1 barcodes to identify the right patient, the right medication and the right device, along with closed loop medicines administration, providing a systematic approach to putting safety first.

The current system of voluntary reporting of adverse drug reactions and device errors isn't sufficient and is not aligned with a culture of safety. Furthermore, very few staff are even aware that the Yellow Card system can be used to raise concerns about medical devices. All parts of the healthcare system need to work in a coordinated way. The shift from analogue to digital must include a mechanism for automatic reporting of harms from medicines and medical devices so that swift actions are taken, communicated and audited to ensure that harm does not persist.

In terms of patient consent, conversations with the professional regulators, the NHS England GIRFT team, the Patients Association and NHS Resolution have identified that improvements are needed. We await the publication of the Principles of Consent and the position statement from the professional regulators. But alongside these, innovations in this area have already been developed which, if scaled and spread, would significantly improve patients' understanding of the treatment planned and would improve quality of care. These include:

- The Oxford Video Informed Consent Tool (OxVIC), an app which videos consent conversations so that patients can watch the conversation again after their appointment.
- Explain my Procedure, which creates animations of procedures which can be used with multiple languages and inserted into the pathways for patient consent.

The work of the MedTech team bringing together industry, regulators, healthcare professionals, providers and patient groups is a great example of how system alignment allows us to go further, faster. I am excited by the potential that this has to demonstrate exemplar working where the views of all involved are seen as equally valuable and there is a mindset of transparency, learning and improvement.

This culture of openness and transparency will also be vital for the new Director of Patient Experience, as the independent speaking up routes for patients and staff via Healthwatch England and the National Guardian will not exist in the future. The forthcoming regulation of NHS managers by the HCPC will also have an important influence on the transparency and accountability of the NHS. My strong advice to the new Director of Patient Experience is to understand what promotes or hinders excellent patient experience and to learn from excellence already established across the NHS, the independent healthcare sector and other sectors. For example:

- Buckinghamshire Healthcare NHS Trust using QUAIL, an AI tool, to read patient complaints and make improvements to patient care and experience, coordinating the information from patients in conjunction with other information from incidents, litigation and Freedom to Speak Up.

- Royal Berkshire NHS Trust, pioneers of Call4Concern, have a process of patient and public engagement to build trustful relationships with patients, families and communities which goes beyond the walls of the hospital, into community and faith groups, to understand and anticipate the needs of their current and future patients.
- Palantir are working with Chelsea and Westminster NHS Trust to develop discharge summaries written in an accessible format for care home staff alongside summaries intended for GPs.
- Written Medicine provides medicine labels with pictograms and standardised instructions in community languages, so that patients and their families have a better understanding of how to take their medicines safely.
- Care Opinion enables patients to give feedback directly to their healthcare provider using an online platform and empowers front-line staff to respond. Through NIHR-funded research, relevant, timely and compassionate feedback has been shown to improve patient experience and outcomes and to improve the morale of the workforce.
- The Patient Experience Library holds the latest and best evidence on patient experience and patient/public involvement, including a red flags tracker for people charged with the task of ‘reading the signals’ of harm.
- Restorative practice, as set out in the Hughes Report, to avoid confrontational approaches and promote transparency and healing for patients, families and staff.
- The Harmed Patient Pathway, developed by the Harmed Patients Alliance and AvMA, intended to achieve better health and wellbeing outcomes for harmed patients and families, better experiences for staff involved in incidents and a positive impact on reducing complaints and litigation.
- The use of online patient feedback by the Health and Youth Care Inspectorate, and the Ministry of Health, Welfare and Sport, Netherlands as the best indicator of the quality of care provided.
- Workforce experience, as measured through the NHS Staff Survey, is one of the most important quality indicators available for NHS providers, as strongly endorsed by Picker, who coordinate the NHS Staff Survey and the NHS Patient Survey. By learning from the best across the NHS, through the staff survey responses, the new National Director of Patient Experience can benefit from excellence demonstrated by healthcare providers and spread and scale up these innovations.

Adoption and spread of these innovations could make a significant improvement to the experience that patients have in the NHS and by listening to and acting on patient feedback, future harm can, and must, be, prevented.

I have learned that the three elements that make all the difference are listening, leadership and partnership working.

I hope this paper shows that change can happen quickly and effectively when the whole system listens, works together and works in partnership with patients and families. A huge amount has already been achieved in a three-year term. I would like to express my heartfelt thanks to everyone involved, including patients and families who have so generously shared their experiences and expertise with me, the fantastic PSC team, the PSC advisory group, members of both Houses of Parliament, and all system partners who have responded with energy and enthusiasm to our recommendations and suggestions. I look forward to continuing the drive to listen intently to the views of patients and the public about the safety of medicines and medical devices and to see all the initiatives described above becoming a reality in England.

# Links

10 Year Health Plan for England: fit for the future - GOV.UK

Accelerating Patient Care with the NHS - Palantir Blog

Care Opinion

Explain my Procedure

Harmed Patient Pathway - Harmed Patients Alliance

Health - Quantium

Health and Youth Care Inspectorate

Medical Devices Outcomes Registry (MDOR) - NHS England Digital

Martha’s Rule - NHS England

Oxford Video Informed Consent Tool (OxVIC): a pilot study of informed video consent in spinal surgery and preoperative patient satisfaction - BMJ Open

Patient Experience Library

Patient Safety Principles - Patient Safety Commissioner

Scan4Safety

The highest quality person centred care for all, always - Picker

Written Medicine