Patient Safety Commissioner

Listening to Patients

Annual Report 2024-25

Patient Safety Commissioner

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Foreword

When I reflect on the journey of patient safety in England, I am struck both by how much progress has been made in some areas, yet how much further we must go. As Secretary of State for Health from 2012-2018, I saw firsthand the impact of listening to patients: their stories of courage, their insight into what needs to change, and demand for a healthcare system that puts safety first.

It was through the tireless work of patient and family campaigners, including Marie Lyon, Janet Williams, Emma Murphy and Kath Sansom over far too many years of raising alarms, that persuaded me to commission the Independent Medicines and Medical Devices Safety (IMMDS) Review in 2018. Their campaigning didn't just lead to the review, it helped shape its focus and recommendations. We owe these women a huge debt of thanks, but the time it took for them to be heard and their concerns recognised, also highlighted a flawed system in need of change. The establishment of the Patient Safety Commissioner is central to that mission, and I am proud to see how the role is flourishing today.

The 2024-25 Annual Report from Professor Henrietta Hughes and her team is a testament to what has been achieved since. Since her appointment in 2022, the Commissioner has made great progress. The Patient Safety Principles, launched in 2024, have provided a framework for all healthcare providers to align with. The 2024 report on redress for those harmed by pelvic mesh and sodium valproate stands as a step toward justice. However, as Prof Hughes has highlighted, the delays in implementing its recommendations on redress are of considerable concern and this must be addressed with the urgency families deserve.

The ongoing work to address barriers, like those faced by people with sensory impairments highlighted in The Safety Gap report, shows a commitment to inclusivity, a fundamental pillar of true safety.

Listening to patients and acting on their concerns is key. The Patient Safety Commissioner's role in developing policy for Martha's Rule, and her leadership in the implementation of the NHS England pilot, has shown the value of an independent champion of patient voice in England.

These achievements show positive progress but they are stepping stones and not end points. As the NHS enters a period of major reorganisation, the role and continued work of the Patient Safety Commissioner is more important than ever. As I look to the future, my hope is that the Patient Safety Commissioner's influence will grow stronger still.

Our shared vision is where every boardroom prioritises the patient perspective, where tools like the Yellow Card reporting system are harnessed to prevent harm before it occurs, and where patients, families and campaigners are listened to and heard by design not only after lengthy and difficult battles.

Prof Hughes has shown that the role of the Patient Safety Commissioner can drive change, but her success depends on the support of all of us – policymakers, healthcare leaders, clinicians and frontline staff, patients and families. The promise of a safer NHS is within reach, and it begins with the courage to keep patients at the heart of everything we do.

Sir Jeremy Hunt MP
Chair of the All-Party Parliamentary Group on Patient Safety and former Secretary of State for Health and Social Care

Introduction

The last year has shown some momentous changes in the way that we listen to patient voices in the healthcare system in England. This has been shown in the intentional deliberative events to involve patients, communities and the public in the development of the NHS 10-Year Plan. I was pleased to give evidence to the Health and Social Care Select Committee on the need for user voices to be central to the implementation of the NHS 10-Year Plan. The pilot of Martha's Rule in 143 hospital sites has already demonstrated that bringing the views of patients and families in detecting deterioration has a life-changing and life-saving impact. I chaired the Martha's Rule Oversight Group to ensure that patient voices, including Martha's parents, Merope Mills and Paul Laity, were involved at every stage, to hear from patients and staff involved in the pilot, and to coordinate the activities of multiple bodies across the health system.

This year also saw the one-year anniversary of the Hughes Report marked by a Westminster Hall debate. Whilst I welcome the heartfelt and warm apology from Minister Dalton and the establishment of the Fetal Exposure to Medicines Service (FEMS) for the North of England, at time of writing patients and families are still waiting for a substantive response to my recommendations for two stage financial redress and non-financial redress for harms from valproate and pelvic mesh caused by healthcare. The Hughes Report sets out a blueprint for all healthcare harms and I hope that it will be valuable for other patient groups including Primodos families. I am very pleased by the progress on the safe use of valproate following the recommendation I made to NHS England with a system approach across the whole patient pathway.

The Safety Gap report I published in March shows that neglecting to include patients, including those with additional needs, affects both the safety and the accessibility of medicines and medical devices. I am grateful to the patients who generously shared their accounts, as well as Prof Mags Watson, the RNIB, the RNID and the Thomas Pocklington Trust and look forward to working with partners to make a substantial improvement to the experiences of patients with hearing and vision loss.

I have continued to broker conversations between patient groups and the health system to highlight the gaps in patient safety and to work together to build solutions which include patient voices in the design and delivery of services. I pay tribute to the patient activists working tirelessly to provide support and use their experiences to bring about positive change. With the Campaign against Painful Hysteroscopy, we have worked with teams at NHS England, the Royal College of Obstetrics and Gynaecology, and the British Association of Day Surgery to ensure that women have the right information to consent as well as options for effective pain relief.

In October, following a public consultation, I published the Patient Safety Principles to act as a guide for leaders in healthcare to make decisions including the patient perspective. These Principles are intended to sit above legislation and regulation and have already been used to support decision making on the Assisted Dying Bill, corporate strategies in regulators and professional regulators and the work of providers in the NHS and the independent sector. At the time

of publication, I await the inclusion of the Patient Safety Principles as part of the NHS Constitution consultation.

Over the course of the year I have worked with global partners, including the World Health Organisation, the Global Ministerial Health Summits, the Patient Safety Movement Foundation, the Health Consumer Advocacy Alliance, Aotearoa of New Zealand, Patients for Patient Safety, and Partners for Patients NGO. This has included presentations in the USA, Geneva, Davos during the World Economic Forum, Manila, Northern Ireland and Scotland.

The role of Patient Safety Commissioner was catalysed by the experiences of incredible patient campaigners such as Marie Lyon, Janet Williams, Emma Murphy and Kath Sansom who had experienced healthcare harm for themselves or their families. The healthcare system they encountered was slow, siloed, defensive, dismissive and lacking in compassion. The Patient Safety Principles, Martha's Rule, the Hughes Report and The Safety Gap show that the healthcare system can be fast, collaborative, inclusive and compassionate.

It is clear that there has been progress on valuing the views of patients in the safety of medicines and medical devices but there is still substantial progress required to ensure that the circumstances leading to the Independent Medicines and Medical Devices Review could never happen again.

I look forward to working with partners, including patient groups, to make this progress and to hold the system and the government to account.

Professor Henrietta Hughes OBE
Patient Safety Commissioner for England

Strategy stocktake

The PSC set out an ambitious strategy at the beginning of 2024 (set out in italics below) and has made substantial progress on delivery.

To drive the alignment of the healthcare system to deliver a just and learning safety culture

1. *We will call for a Safety Management System to reduce harm to as low as possible*
2. *We will call for improvements in signal detection through the MedTech strategy and mandatory reporting of Yellow Cards*
3. *We will call for an overhaul of the complaints procedure and clinical negligence in the healthcare system, promoting restorative practice to support patients, families and healthcare workers*

The PSC developed and published the first Patient Safety Principles, following a public consultation. These incorporate the requirement for a Safety Management System for the healthcare sector. She led a widescale engagement programme across the healthcare sector to raise awareness of the Principles and encourage embedment. To date, the Patient Safety Principles have been incorporated into the ABHI Compass Code for clinicians manufacturers, the consultation on the NHS Constitution, the work of the NHS, and independent sector providers.

The PSC has been represented on the NHS England Safety Management Systems coordination group and contributed to the HSSIB's report 'Safety management: accountability across organisational boundaries'. This recommended that the DHSC and NHS England use its findings to inform the development of the 10-year health plan and the NHS Quality Strategy to encourage further exploration of how safety

'I want to push the boundaries of the role' – Joy Ellery

Joy Ellery is one of two Patient Safety Partners at the Royal Marsden NHS Foundation Trust in London. She has a background in the NHS and worked in Research and Development and in total, spent 30 years in the service.

When she retired in 2014 and while receiving treatment at the Royal Marsden, she saw an ad for the patient safety programme and applied.

'I listen as a patient, contribute, and give feedback. I think there is real benefit that we are not employees – we can give our opinion and it is easier for us to be a critical friend. The feedback on the new roles has been very positive. We are told by senior members of staff that they welcome our input.'

Joy is extremely enthusiastic about her PSP role. 'It feels good,' she says. 'I am using my mind and keeping alert. I read hundreds of pages in preparation for the meetings and they are interesting because they are about patient safety – it makes me think. I meet interesting people and it keeps me at the top of my game.'

She has big ambitions for the role. 'I want to push the boundaries of the role. I have already sat on an interview panel for a risk role and we can help with how the organisation deals with risk. We are beginning to be directly involved in investigations and we want to do some training for staff.

'I'm doing it to help the hospital which helps me,' she concludes.

management principles could be applied in healthcare settings to improve patient safety. She promoted the work of the HSSIB in this area, specifically in 'Recommendations into Impact' and visited BA and Easyjet as part of a programme to establish and learn from the airline industry which takes a proactive approach to safety using a safety management system approach.

The PSC inputted to both the Darzi review of the NHS and the Dash review of patient safety organisations as well as the 10-year health plan. She co-chaired the Patient Safety Leaders informal network, contributed to the new WHO Global Patient Safety Charter, and responded to a range of consultations.

The Commissioner held meetings with the chair of the Health and Social Care Select Committee and the Chairs of a number of APPGs including First Do No Harm, Beyond Pills, Patient Safety, and Women's Health.

The PSC was also a regular voice on patient safety across national media and delivered many keynote presentations including at WHO, the Global Ministerial Health Summit, and the Health Equity Action Lounge @ Davos during the World Economic Forum 2025.

She acted as an advisor to the MedTech Strategy Programme Board. Her influence succeeded in increasing patient engagement by bringing in the patient voice to sit beside that of manufacturers and clinicians. The new patient engagement forum for the programme means that new devices are now developed with the patient in mind. She also brought representatives from the RNIB and the RNID into the group to give people with sensory impairment a direct input into the programme.

She regularly engaged with the MHRA on Yellow Card reporting, checking on feedback and actions, promoted the agency's Yellow Card Week and presented to its Board. She directly engaged with the EMIS system to improve Yellow Card reporting rates. This led to a series of changes that made Yellow Card reporting more visible and easier for users to access. She also engaged with the Commission on Human Medicines on embedding its work into clinical practice.

The PSC collaborated with patient safety colleagues in New Zealand to learn about restorative practice and worked with providers who are using restorative practice for patients and staff. She lent her support to Action against Medical Accidents (AvMA) on its harmed patient pathway.

The Commissioner worked with system partners to streamline complaints and called for national learning on complaints as exists for clinical incidents. She promoted innovation in clinical negligence, including the use of AI in assessing legal bundles.

To support initiatives which amplify all patient voices and empower patients to make informed choices about their care.

1. *We will drive the development and design of Martha's Rule to empower patients and families to seek a rapid review*

2. *We will call for informed consent and support decision making so all patients are fully informed about the benefits, risks and alternatives when a medicines or medical device is used*

3. *We will support calls for greater transparency of payments and for registers of interest for all healthcare professionals*

The PSC was tasked with developing the policy for Martha's Rule, a new initiative to provide families with the means of seeking a rapid review if they had concerns about deterioration in a patient. She was appointed as the independent Chair of the Martha's Rule

Oversight Group by the former Secretary of State for Health and chaired monthly meetings bringing together Martha's family, regulators, professional bodies, and the DHSC to oversee implementation of the initiative.

She conducted a widescale engagement programme on Martha's Rule comprising: visits to NHS trusts, including pilot sites and independent sector providers; regular meetings with the family and patient groups; talking to staff groups including the British Association of Critical Care Nurses, the Faculty of Intensive Care Medicine, the Association of Anaesthetists, and the Royal College of Surgeons of Edinburgh; speaking at patient forums; addressing global conferences; and engaging with partners in Wales, New Zealand, the US and Australia.

The PSC worked with professional regulators to develop the position statement on consent and with NHS England, GIRFT, and partners on the principles of consent.

She collaborated with royal colleges on addressing painful outpatient gynaecological procedures and the safe prescribing of antidepressants. She also promoted NHS Resolution resources on consent and the Montgomery vs Lanarkshire ruling that affirmed the patient's right to self-determination in treatment decisions.

The PSC worked with patients, the mesh campaign group Sling the Mesh, regulators, trade bodies, and with DHSC officials to ensure that patient voices are involved in transparency of payments to clinicians and the publication of the results of the register of interest pilot.

To advocate for partnerships which embed patient safety and patient voice throughout the healthcare system

1. *We will work with healthcare organisations to ensure that Patient Safety Partners are embedded across England and are upskilled as required*
2. *We will advocate for the promotion of a patient safety culture across the health system including training in patient safety for board members*
3. *We will join cross system and global initiatives to advocate for patient voices to be central to the design and delivery of healthcare*

The PSC collaborated with Patient Safety Learning and NHS England to support the Patient Safety Partner network, meeting PSPs on trust visits and speaking at network meetings.

She engaged with ministers and officials, Parliamentarians, manufacturers, trade bodies and national leaders. The Commissioner called for patient safety to be included in planning guidance, worked with NHS Providers to ensure patient safety training is available to board members, and called for the NHS England Board to have training in patient safety.

As well as co-chairing the patient safety leaders network, the PSC was an active member of the National Patient Safety Committee and a member of the Emerging Concerns protocol.

She is a Member of the Leng Review Group of Physician Associates and Anaesthesia Associates and the NIHR Patient Safety Research Collaboration advisory board (SafetyNet) and attended the 'Research governance workshop: learnings from the Infected Blood Inquiry for the future'.

The Commissioner inputted into Ministerial roundtables on Women's Health and Dementia and Partner Council meetings as part of the 10-year plan development, bringing her unique perspective of listening to patients.

Spotlights

Principles

The development of the Patient Safety Principles was a collaborative process designed to ensure they are practical, inclusive, and meaningful. The process began by drafting an initial version that captured the core elements of safe patient care.

Then feedback was collated from key stakeholders, including the NHS Race and Health Observatory, the HSSIB, the CQC, the Patients Association, NHS Providers, and the GMC, to refine the Principles. This stakeholder input highlighted some areas for improvement on the draft principles.

Following this review, a public consultation was launched on 24 July and ran until 6 September to provide the opportunity for the public to input their views. The consultation invited feedback from healthcare professionals, patients and advocacy groups.

Over 800 people submitted responses which were then analysed and went on to directly inform the final version of the Principles, which were published on 23 October.

On publication, the PSC said: 'Every day we have to make tough choices, balancing benefits and risks. Those choices impact on patient safety, right now or far into the future, with effects that we might have never intended or anticipated.

'There are too many tragedies where people have been harmed by a healthcare system that is slow, siloed and disjointed and does not listen.

'We need a set of guiding principles that, when we are faced with tough choices, will help us to make the right choices. When we are unsure, they will help us to know we are doing the right thing. When we feel unsafe, when the healthcare system asks the impossible and when it is not putting patients at the heart of decisions, we will have a north star to guide us to a supportive and compassionate approach. The Patient Safety Principles will help us to do all of these. They will sit in the background, be part of our professionalism, directing our daily actions and interactions and the norms that build a culture of safety for all.'

The Patient Safety Principles were endorsed by health leaders across the system including Professor Lord Darzi and NHS England Medical Director Professor Sir Stephen Powis.

Since the launch, the PSC has conducted a wide-ranging engagement exercise to encourage organisations to embed the principles on an individual, team and

organisation 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.

The PSC has engaged proactively with the proposed Assisted Dying Bill by conducting a principles-based analysis of the bill, at the request of Kim Leadbeater MP. Using this approach, she aimed to evaluate how effectively the draft legislation and initial amendments align with the Patient Safety Principles, particularly around transparency, patient-centeredness, and accountability. Following this preliminary assessment, she offered initial suggestions on possible methods to enhance the embedding of patient voices within the legislative framework. Incorporating the Principles into the Bill can embed patient voice into its workings and ensure a better, safer bill.

Following close work with Circle Health Group, its Patient Safety Strategy 2025-2028 incorporates the Principles. The patient safety strategy objectives align with the Principles and are embedded within its organisational governance and operational activities. The patient safety strategy objectives take the wording of the Principles and integrate them into operational approaches with clear and practical goals. This alignment and integration illustrates how healthcare organisations might use the Principles to set objectives and evaluate patient safety outcomes.

The PSC is currently in the process of exploring ways to contribute to the forthcoming refresh of the Nursing and Midwifery Council (NMC) strategy. By engaging with this strategy development, she seeks opportunities to highlight how the Patient Safety Principles, specifically those relating to transparency, equitable care, and patient-centered practice, might enhance the strategic direction of the NMC.

Her input will support the NMC in further strengthening its strategic commitment to patient safety and quality improvement across nursing and midwifery practice.

The PSC is looking to contribute to the General Medical Council's (GMC) review of its corporate strategy by offering insights grounded in the Patient Safety Principles. The aim is to encourage consideration of how the Principles can be reflected within the GMC's revised strategic framework.

The PSC is also in discussion with the Care Quality Commission (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.

They define what high quality care looks like from a patient perspective and help providers understand how their services will be assessed during inspections. Recognising the influential role these Quality Statements play in shaping standards of care, the PSC has begun exploring how explicitly incorporating the Patient Safety Principles could drive improvements in patient care and safety outcomes.

She has also engaged with the Department of Health and Social Care on the potential inclusion of the Patient Safety 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 Patient Safety Principles into this document, there is an opportunity to reinforce the centrality of patient safety as a core commitment across all healthcare services.

The Safety Gap

A number of people with sensory impairment contacted the Commissioner when she first took up her role in September 2022 outlining how they were having difficulty accessing medicines safely and using specific medical devices.

This was because these devices were designed without their input and little thought had been given to how medicines could be accessed by patients with sensory impairment.

At the same time work on the digitalisation of the electronic patient information leaflet revealed how people with visual loss were finding it difficult to read leaflets which were produced in small print. The PSC then worked with the RNIB and uncovered high levels of unmet need.

The Commissioner decided to contract a researcher to shine a light on this unmet need. The research conducted by Professor Mags Watson focused on diabetes and vision loss because this group of patients has to use both medicines and medical devices every day.

The result was *The Safety Gap, the Safety and Accessibility of Medicines and Medicine Devices* report, that was released in March 2025. The research found that patients are being put at risk when using medicines and medical devices if safety is not considered upfront.

It recommended that the views of patients are incorporated when designing and manufacturing devices and ensuring that medicines are made accessible for those with a sensory impairment.

The PSC published the report on her website and in a range of accessible alternate formats including braille, audio, and BSL.

‘Lots of areas would like a PSP of their own’

Colin Fiske is a Patient Safety Partner with United Lincolnshire Teaching Hospitals NHS Trust. After spending over 30 years in the police service, on retirement he wanted another challenge and after moving to Lincoln to be close to his partner’s family, he saw an advert in his local GP surgery to join the local patient group. This led to membership of the hospital patient panel and then to becoming a PSP in September 2022.

‘It has been really interesting being a PSP,’ he says. ‘The hospital had a good plan for implementing PSPs and now there are lots of areas that have seen the value we can bring and would like a PSP of their own. The demand for PSPs from other committees and groups is very welcome. Although there is only four of us, this is set to expand soon.’

His new role is completely different from policing. The main challenge has been understanding all the terms the NHS uses, he says. ‘This is about representing the patient’s perspective and ensuring the patient always remains the focus.’ Colin and a PSP colleague were part of the hospital’s PSIRF implementation group and amongst many other meetings, he has also just joined the maternity and neonatal oversight group.

He feels PSPs are part of the patient safety team and very involved in the operation of the hospital. He views the status of the PSPs as a key factor. ‘We are all volunteers which makes it much easier for us to speak out and challenge things. It is a great job, but you must continue to remember it is not about you – it is about you representing the patients. Prospective PSPs should always think what they can bring to the role to help the hospital improve the safety for all patients.’

Martha's Rule

The year saw Martha's Rule develop as 143 pilot sites introduced the new initiative that provides patients and families a means of escalating concerns about deterioration. The new initiative is named after Martha Mills, who died from sepsis aged 13, in 2021, having been treated at King's College Hospital, London, after her family's concerns about her deteriorating condition were not responded to.

The initiative, which is being implemented by the patient safety team at NHS England under the leadership of Aidan Fowler, National Patient Safety Director, aims to provide a consistent and understandable way for patients and families to seek an urgent review if they, or their loved one's, condition deteriorates and they are concerned this is not being responded to.

Since establishing the work in November 2023 and being asked by the then Secretary of State to chair the oversight board, the PSC has worked closed with NHS England to ensure smooth implementation by bringing together all elements of the system, including royal colleges, regulators, and professional bodies. The result has been a joint statement from the GMC, NMC and the CQC and extensive engagement across the system explaining how the initiative works.

The initial data on the impact from the pilot trusts was positive. It showed that there were at least 573 calls made to escalate concerns about a patient's condition deteriorating in September and October 2024, including from patients, their family, carers, and NHS staff. Around half (286) of these calls required a clinical review for acute deterioration, with around 1 in 5 (57) of the reviews leading to a change in the patient's care – such as receiving potentially life-saving antibiotics, oxygen or other treatment – while remaining on their current wards. In addition, in the first two months alone, 14 calls made via Martha's Rule resulted in a patient needing urgent transfer to an intensive care unit.

Of the initial 573 calls:

- 15% were from patients
- 76% were from family, carers or designated advocates
- and 9% were from NHS staff.

Calls that did not require a clinical review for deterioration were relevant in other ways, enabling patients and families to escalate concerns to staff and for these to be swiftly acted upon. They also gave patients, families and staff the opportunity to seek a review if they had concerns.

Prof Hughes reflected: 'I am delighted that the initial results from the Martha's Rule pilots demonstrate how effective the new initiative is in providing a mechanism whereby patients and families can act if they believe a patient is deteriorating. This initiative will obviously lead to a significant improvement in patient safety and will change the way we listen to patients.'

Merope Mills and Paul Laity, Martha's parents, said: 'We are really pleased to see the immediate positive impact Martha's Rule has made in the hospitals that have introduced it so far. It is our view that listening to the voices of patients and their families makes for the best and safest medicine. Were it to be implemented nationally, it would greatly improve care, help change the culture and save lives.'

Redress

Throughout the year, the Commissioner continued her calls for a government response to the recommendations set out in the 2024

Hughes report on options for redress for those harmed by valproate and pelvic mesh.

In July 2024, she welcomed confirmation that the government was looking at the recommendations for a redress scheme. 'The only way to understand the devastating experience of harm is to hear from patients directly,' she said. 'I expect a full response to be provided to patients at the earliest possible opportunity.'

In December, the patient safety minister Baroness Merron pledged to work at pace on financial redress. In a written answer, she told the House of Commons that 'the Government was carefully considering the valuable work done by the Patient Safety Commissioner in setting out options for redress and that the government would be providing an update to the Hughes at the earliest opportunity'.

Early in 2025 patients and campaigners gathered at two round tables to engage the minister and urge the government to respond to the recommendations.

On the first anniversary of the Hughes report in February, the PSC repeated her call for a response to her recommendations: 'Patients and families are suffering right now, and whilst the Government reviews my recommendations, it does not put their problems on hold,' she said. 'Patients are in pain, need equipment and the delay is having a corrosive effect on wellbeing as they are being asked to recount their experiences again and again.' A Westminster Hall debate was also held at which MPs, Professor Hughes and campaigners repeated their calls for redress.

MedTech

The Commissioner was appointed as an independent advisor to the MedTech Strategy Board to ensure that the patient voice was heard loud and clear when implementing the strategy. She recommended that a patient engagement forum be established to support the strategy and to ensure that the views of patients were central to it, alongside that of clinicians and manufacturers.

This was duly established and is succeeding in bringing together these three groups to ensure that new devices are developed with patients in mind. Following the publication of The Safety Gap report the PSC specifically brought the RNIB and the RNID into the group, ensuring that people with sensory impairment were represented.

Prescribing

Antidepressant prescribing is at record levels in England, with around one in five adults receiving these medicines for a range of mental health conditions and chronic pain. Prescriptions have doubled since 2010 with around half of patients taking antidepressants long-term.

While NICE recommends antidepressants as one of the main options for 'more severe' depression, non-drug alternatives such as self-help, psychological interventions and exercise are considered more clinically effective and cost-effective in 'less severe' depression.

To ensure antidepressant drugs are prescribed to patients only where the benefits outweigh the potential harm, NHS England is encouraging ICBs to address inappropriate antidepressant prescribing and to consider commissioning services for patients wishing to reduce or stop antidepressants when their clinical condition allows.

At times patients struggle to stop taking anti-depressants as the symptoms of withdrawal can mimic general anxiety. It is difficult to follow guidance on dose reduction using tablets and the liquid version is not always available to all GPs and is more expensive.

The PSC actively supported the Beyond Pills campaign throughout the year. This campaign strives to move UK healthcare beyond an over-reliance on pills by combining social prescribing, lifestyle medicine, psychosocial interventions and safe deprescribing to improve outcomes and reduce health inequalities.

The Commissioner convened a meeting with NHS England and the Royal College of Psychiatrists which agreed a joint desire to unblock this issue by conducting a pilot of safe deprescribing. A request for pilot funding has been made to the Secretary of State and the group is awaiting a response.

Valproate

While the PSC waited for the government's full response to the recommendations set out in her report into redress options for those harmed by valproate and pelvic mesh, she continued to improve the safe use of the most potent teratogenic medicines.

The PSC made a recommendation to NHS England, which it accepted, to have a fully funded and resourced system for improving the safe use of the most potent teratogenic medications, through a National Quality Improvement Programme for Integrated Care Systems, starting with the safe use of valproate.

The Commissioner believes that this should be expanded to cover any medication with a Pregnancy Prevention Programme by September 2025.

The result of this improvement programme was very positive and saw improvements in valproate prescribing:

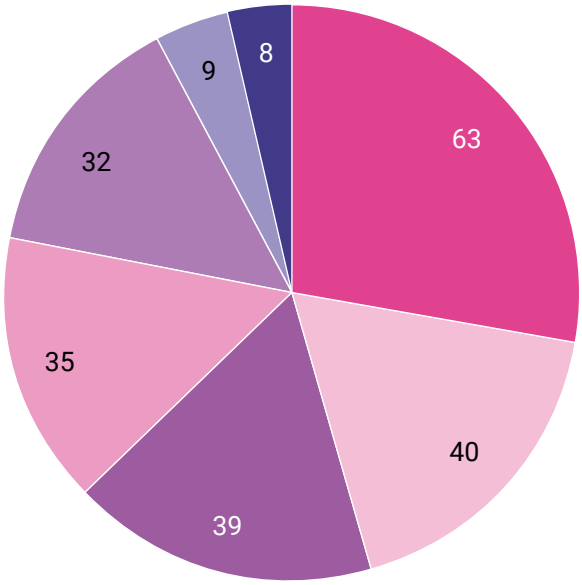
- a 53% reduction in initiation in girls aged 0-12
- a 60% reduction in women aged 13-54 started on valproate
- a 65% reduction in women re-starting valproate after a break of six months
- and at least 9 out of 17 mothers having active management of valproate if it was prescribed during a month in which the woman was pregnant.

Meanwhile NHS England has commissioned two sites at Newcastle Hospitals NHS Foundation Trust and Manchester University NHS Foundation Trust to run a pilot of a new Foetal Exposure to Medicines Service (FEMS) scheme for people from the North of England.

The pilot clinical service provides expert assessment, diagnosis and advice for children and adults who have problems following exposure to certain antiseizure medicines (also known as anticonvulsants) before birth. As at month three of the first year, 43 referrals have been accepted into the service.

Correspondence

In the year to April 2025, the level of correspondence to the PSC was down compared with the previous year, and much of it related to issues other than the Commissioner's primary remit of medicines and medical devices. Patients who contacted the PSC about areas that were outside the scope of the PSC were signposted to the part of the healthcare system best placed to address their questions. The highest volume of correspondence was from people raising complaints and concerns with the care they or a loved one had received and those wishing to share their experiences with the Commissioner. From this correspondence it is clear people continue to find the NHS complaints process difficult to navigate and unhelpful, with many asking the Patient Safety Commissioner to intervene directly in their individual cases. Correspondence about mesh and valproate continued to be received, with many seeking an update on the long-awaited government response to the Hughes Report on redress options. The Commissioner is grateful to everyone who has been in touch and shared their experiences.



- Individual concerns and complaints about healthcare (63)
- Hughes Report (mesh, sodium valproate, redress enquiries) (40)
- General enquiries (39)
- Other medicines/medical devices (35)
- Out of scope (other health related issues) (32)
- Out of scope (non-health related) (9)
- Martha's Rule (8)

Business planning

We set out four key areas for work in our business plan for 2024-25. We have published the Patient Safety Principles following a public consultation and worked with a wide range of organisations across the healthcare system to implement and embed these. We published The Safety Gap, a research report into the safety and accessibility of medicines and medical devices for people with a sensory impairment, making recommendations to improve patient safety and experience. Our planned work on the Atlas of Powers was overtaken by the second Dash review into the patient safety landscape. We reviewed our plan to explore Closed Loop Medicine Administration (CLMA), working collaboratively with the Chief Pharmaceutical Officer's Clinical Fellow project on this topic.

Finance

While the OPSC's operational line of responsibility runs to the Health and Social Care Committee, its financial responsibility and requirement to manage public money effectively runs to the Department of Health and Social Care. As such, the internal and external audit processes, in a financial sense, are conducted by the DHSC and information on these can be found via the Department. The OPSC retains the use of the Department of Health and Social Care's banking facilities to run day-to-day operations. The Commissioner's annual expenditure is amalgamated within the Department's Annual Report and Accounts.

For more information about the Office of the Patient Safety Commissioner, visit
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