



Annual Report 2023-24





Patient Safety Commissioner

Annual Report 2023-24

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Foreword

Those who champion patient safety around the world are sometimes accused of being more interested in health service failures than successes. Yet keeping patients safe from avoidable harm should be a priority for all health systems.

As a cancer surgeon, a former Government health minister, and as leader of the longest running patient safety research centre in the UK, I know how vital this is.

Solving the blight of unsafe care depends on openly and courageously addressing it. Tens of thousands of NHS patients suffer clinically significant adverse effects because of errors in their treatment. As well as causing trauma to individuals and their families, these errors, including the minor ones, are an immense drain on NHS resources.

Key to the task of reducing the toll of harm is involving patients and their families. Their concerns often provide early warning of future disasters which might have been avoided had they been listened to and acted on.

In the last year we have seen the consequences when these concerns are ignored: in the Lucy Letby case, where a neo-natal nurse was jailed for the murder of seven babies and the attempted murder of six others, and in the Infected Blood scandal in which an estimated 30,000 people were given contaminated blood transfusions over a 20-year period.

The Patient Safety Commissioner for England was created in 2022 in response to the Independent Medicines and Medical Devices safety Review which demonstrated that patients' voices had not been heard. Sodium

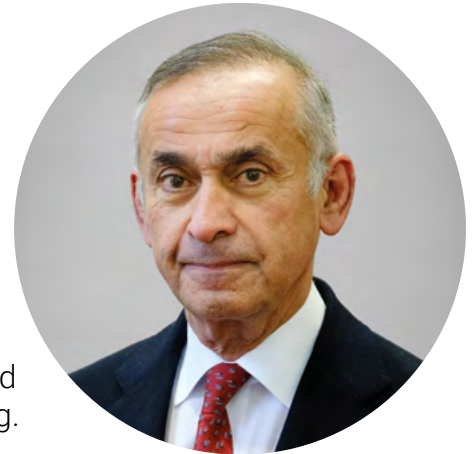
valproate and pelvic mesh were just two treatments that caused widespread harm and suffering.

The Commissioner's role is to listen to patients, amplify their voices in the NHS and to government, help them achieve justice, and ensure the lessons of past mistakes are learned.

To this end the Commissioner has set out options for compensation for those harmed by sodium valproate and pelvic mesh, overseen the introduction of Martha's Rule which enables patients to ask for a rapid clinical review if their condition or that of a loved one deteriorates, and initiated monitoring of the safe use of the most potent teratogenic medications. These and other measures, including improvements to the Yellow Card reporting system and to pulse oximeters for patients with darker skins, represent real advances in the drive to reduce harm.

In the past, patients who suffered harm during their care were regarded as the 'cost of doing business'. That view is no longer acceptable. The work of the Patient Safety Commissioner demonstrates what can be achieved with the right focus, energy and commitment.

Safety is not like quality, something we strive for – it is something we cannot do without.



Professor the Lord Darzi of Denham

OM, surgeon and co-director of the Institute of Global Health Innovation, Imperial College London



Introduction

The past year in my role as the Patient Safety Commissioner for England has been a momentous one for my mission to promote patient safety, amplify patient voice, and introduce restorative practice, as is demonstrated by this annual report.

As well as raising patients' concerns about medicines and medical devices, I have set out a redress scheme for those harmed by valproate and pelvic mesh and developed a plan to introduce Martha's Rule, a means of enabling patients and families to seek a rapid clinical review when a patient's condition is deteriorating.

Martha's Rule signals a shift to the culture we need to see in the way patients are listened to by the health system. The initial policy sprints which brought the whole health system together demonstrated that where there is the will to improve patient safety, we can do so – and swiftly. The recommendations were on the Secretary of State's desk within a matter of weeks.

My wider recommendations on changing the health system for the benefit of patients have been accepted and some have already been, or will shortly be, implemented.

We are now developing systems in ICSs to monitor the safe use of the most potent teratogens, meaning fewer babies will be born with birth defects; the risks of acne medication isotretinoin, which can cause severe side effects, are now tightly monitored; and the antibiotic fluoroquinolone is now only used when other antibiotics are inappropriate.

But although improvements have been made, more needs to be done. And this will require cultural change and exemplary leadership.

Without a just and learning culture and transparency, we will continue to see harm happening again and again. Therefore, it is up to patient safety leaders to take ownership of patient safety, raise hope, change attitudes, and set an exciting, shared vision to minimise avoidable harm.

I want us to imagine a future where patients are partners, those providing care are helped keep their patients safe, and every part of the system works together to make that happen. This future strips power away from those who cling on to it at the centre and shares that power with patients and colleagues, so we plan and learn together in a just culture. And for this change to happen, we need a future facing safety management system.

This past year has also seen huge strides on the global stage with the development of the first WHO patient safety charter that I helped frame during summer 2023. This outlines the core rights of all patients in the context of healthcare safety and seeks to assist governments to ensure that the voices of patients are heard and their right to safe healthcare protected.



**'imagine
a future
where
patients are
partners'**



As the WHO Director-General Dr Tedros Adhanom Ghebreyesus reminds us, patient safety is a collective responsibility and health systems must work hand-in-hand with patients, families, and communities,

'health systems must work hand-in-hand with patients, families and communities'

so patients can be informed advocates in their own care, and everyone can receive the safe, dignified, and compassionate care they deserve.

Reflecting back on the year, I am grateful for the support I have received from all parts of the system – providers, regulators, professional bodies, private organisations, manufacturers, and patients themselves. Their input has been fundamental to making change happen.

It is clear from the many conversations I have and continue to have that many people also want to see change happen and I hope that over the coming year, we will work together to improve the experience of patients. I am also extremely grateful to all the patients and patient representatives who have contacted me and worked with me.

In this short timescale, I have already seen the conversation about patient safety change and because of this, I am optimistic that together we can really change the landscape for patient engagement and partnership to keep people safe.

Dr Henrietta Hughes OBE

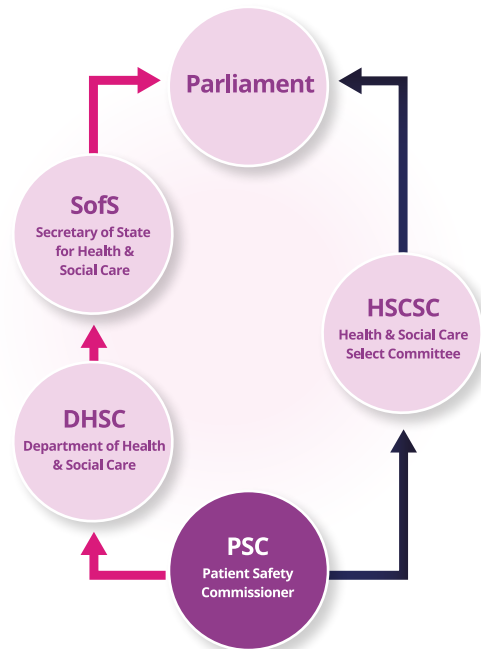
Patient Safety Commissioner for England

Structure

While the Patient Safety Commissioner is independent of government and the healthcare system, the PSC's funding is provided by the Department of Health and Social Care (DHSC). The PSC remains accountable to Parliament including through the Health and Social Care Committee. The Office of the Patient Safety Commissioner (OPSC) is resourced by civil servants and maintains a working relationship with the DHSC. This helps it to influence government, offer constructive advice on policymaking, and amplify the patient voice into the Department.



While the OPSC works constructively with the Department, it remains outside of it, and is guided by the Patient Safety Commissioner's strategic priorities. This means the Office can focus on what matters to patients and advocate for that with the Department and other parts of the healthcare system. In addition, a constructive, working relationship with the Department helps the OPSC most effectively utilise the backend processes it needs to function, which is important to ensure the effective use of public funds.



Advisory Group

The PSC Advisory Group is a statutory requirement and brings together a range of influential voices with a shared vision of promoting patient safety and amplifying patient voices. Members provide support, insight, advice, and challenge to the Commissioner, acting as a sounding board to inform her strategic priorities and direction, with particular reference to ensuring the PSC follows a 'patients first' approach in discharging her duties. The Group also helps raise the profile of the Commissioner's work through members' networks, leveraging the power of their influence on behalf of the PSC and shares good practice within their own organisations and beyond to champion patient voice.

The Advisory Group members are: Louise Ansari; Rabbi Harvey Belovski; Helen Buckingham; Saffron Cordery; Baroness Julia Cumberlege; Mike Durkin; Ian Green; Habib Naqvi; and Rachel Power.

A member of the PSC Advisory Group, Louise Ansari, chief executive of Healthwatch England, reflects on working with the Commissioner to improve patient experience.

The PSC Annual Report 2023-24 is published amid challenging times for the health system. Though patients in England still broadly experience a good standard of care from the NHS, accessing care remains difficult for too many across the country, particularly those from low-income backgrounds. Navigating a complex system of health services can be frustrating, whether for carers, families or patients themselves.

And yet there are grounds for optimism as we look ahead. Healthwatch England, the Patient Safety Commissioner and other bodies representing patients are clear about how we can improve patient experience across services. At the heart of this is listening to patients.

We have been pleased to support the Patient Safety Commissioner's calls to introduce Martha's Rule across England, ensuring people have access to a rapid review from an independent team if they are worried about their, or a loved one's, condition. This initiative will undoubtedly improve a culture of listening in the NHS and may well save lives.

We are also united in our belief that we must improve the system of listening to, and acting upon, complaints. Too often, complaints are seen negatively by those planning and delivering services not as a learning tool that they can use to improve care for patients. For patients, it can be unclear who they should go to with

complaints and even once made, complaints often go unanswered. We look forward to working together to improve the complaints process and ensure that listening to patients leads to improvements in services.

And, of course, our organisations believe there are huge opportunities to improve access to healthcare through technology. The growth of the NHS App and digital access to patient records is to be welcomed, though again we are clear that patients must be informed about benefits and risks and be put at the heart of decision-making about tech-enabled care.

Working with Henrietta and her team on the above issues and many others has been a pleasure. I congratulate the Office of the Patient Safety Commissioner on an impactful last year and look forward to continuing our work to support, champion and protect patients.



'we must improve the system of listening to and acting upon complaints'

Strategy

During her first 16 months in post, the PSC focused on pelvic mesh, valproate and culture change. These priorities were largely influenced by the origins of her role, which was set out by the Independent Medicines and Medical Devices safety Review, and the medical interventions that it highlighted.

The PSC role is relatively narrowly defined. It covers the promotion of patient safety and patient voice with regards to medicines and medical devices. Fundamental to this is the creation of a just and learning safety culture.

In late autumn 2023, the Commissioner's team undertook work to refresh the strategic priorities and identify overarching themes based on what she was hearing from patients.

The new strategy is an ambitious one and runs until the end of the PSC's first term in September 2025. When developing the strategy, the team spoke to key stakeholders and found there was very close alignment with their priorities.

In January NHS England accepted the PSC's recommendation for a new monitoring system of the most potent teratogenic medications through a National Quality Improvement Programme for ICSs, starting with the safe use of valproate before expanding to cover any medication with a Pregnancy Prevention Programme

As the PSC was hearing about a wide range of medicines and medical devices, her updated strategy moved away from focusing on two specific treatments and instead expanded its focus on culture change.

The strategy is based on three overarching ambitions, with three operational priorities, each with three core strands:

The first strand is to:

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

The second is to:

- support initiatives that amplify all patient voices and empower patients to make informed decisions about their care when considering the use of medical devices or medicines.

The third strand is to:

- advocate for partnerships that embed patient safety and patient voice throughout the healthcare system.

The strength of the Office of the Patient Safety Commissioner is its ability to work with, and through, other organisations in a collaborative and supportive way to obtain traction in a health system which is complex and confusing for patients and staff. Through this collaborative approach, the PSC can raise issues, identify problems, and signpost people to the relevant organisation.

She can shape the debate and bring disparate groups together to solve problems and make change happen. And vitally, she can amplify patients' voices into government.

There are many organisations with a responsibility for patient safety in England and the Commissioner's role is to bring them together to align their goals and activity to put patients at the heart of everything the health system does.

In developing a just and learning safety culture, the PSC will call for a Safety Management System for the healthcare system to reduce patient harm in relation to medicines and medical devices to as low as reasonably possible.

She will also call for improvements in the way in which the side effects of medicines and medical devices are identified through the MedTech Strategy and mandatory reporting of Yellow Cards.

Her strategy includes calling for an overhaul of the complaints process and clinical negligence, promoting restorative practice to support patients, families, and healthcare workers, and ensuring that when something goes wrong with a medicine or medical device, patients receive a non-adversarial response.

After a meeting in 2022 with families of young people who had taken isotretinoin (Roaccutane), an anti-acne medication, and suffered from side effects including mental health issues, the PSC raised their concerns to the MHRA. In October 2023, the agency issued advice introducing additional oversight of the initiation of the medication in patients under 18 years and strengthened assessment and monitoring of mental health and sexual dysfunction issues

'It is a privilege to be working to ensure the patient's voice is heard'
- Sue Strudwick



Sue Strudwick is a Patient Safety Partner at Kingston Hospital in south west London and was recruited in March 2022.

Sue believes the key to the success of the development of the role was the preparation by and ongoing support from the patient safety specialist.

'This preparation helped enormously in being accepted within the organisation,' she says. Another positive was that the acute and local community trusts collaborated to appoint their PSPs at the same time and all undertook the induction and training together.

'Communication is key, with confidentiality remaining paramount,' she says. 'Words are remembered and how they are interpreted is crucial. Representing the patient voice through our questions and comments can be really productive or the opposite! And the use of acronyms continues to be a problem across the board and makes it much harder to understand the plethora of reports.'

The PSPs' varying interests and strengths have also helped in developing the role with the rest of the team. 'We are more effective if we are interested and enthusiastic, bringing our experiences and skills to the role, with tasks being allocated according to each individual's abilities.

'Of course, there are challenges,' she adds. 'Lack of time is the biggest issue and PSPs can't be every patient, so we must work hard to listen to patients constructively and reflect their concerns.

'However, it is a privilege to be working to ensure the patient's voice is heard and acted upon at the heart of the NHS.'



In the second strand of the strategy, the PSC pledges to drive the development of Martha's Rule to empower patients and families in hospital to seek an urgent rapid review if their condition, or that of a loved one, is deteriorating.

The PSC will also call for informed consent and supported decision-making so all patients are fully informed about the benefits, risks, and alternatives when a medicine or medical device is used as well as for greater transparency of payments, including registers of interest for healthcare professionals.

The third strand of the strategy is to advocate for partnerships that embed patient safety and patient voice by working with healthcare organisations to ensure Patient Safety Partners are installed across England and are upskilled as required.

Advocating for a safety culture across the health system will include training in patient safety for board members. And the PSC will join cross-system and global initiatives to ensure patient voices are central to the design and delivery of healthcare.

When these strategic ambitions are achieved, patients will receive healthcare in a planned and proactive system that joins up care around their needs, supported by leaders in a just and learning culture.

The patient voice will have equal weight and will be listened to and acted upon in relation to patients' own care and patients will be partners in the design and delivery of healthcare. Risks will be identified early as patients, families and staff will be able to raise these in a psychologically safe and transparent environment and the right mitigations will be put in place to keep people safe.

Patients raised concerns about the risk of disabling and long-lasting side effects from the antibiotic fluoroquinolone, which the PSC raised to the MHRA, prompting a review. In January, the MHRA issued a drug safety update informing prescribers that the medication can only be used when other commonly recommended antibiotics are inappropriate

Year at a glance



Spring 2023

- in May, the PSC issued a template letter for patients to use when informing their GP about side effects from pelvic mesh
- in June, the Commissioner began work to set out redress options to government for those harmed by pelvic mesh and valproate following a request from the minister for patient safety
- June also saw the launch of the PSC website, a new channel for people with the shared goal of patient safety



- in the same month, at the World Patient Safety Movement Summit in California, the PSC met Merope Mills, the mother of Martha, who died unnecessarily aged 13 of sepsis, prompting the campaign for Martha's Rule to enable patients to ask for a rapid clinical review if their condition, or that of a loved one, deteriorates



Summer 2023

- in August, the PSC called for improvements to patient safety reporting systems and training for non-executive directors following the sentencing of Lucy Letby, a neonatal nurse who murdered seven infants and attempted the murder of six others at the Countess of Chester hospital
- in the same month, the Commissioner advised the former Secretary of State to introduce Martha's Rule
- later in August, the PSC called for patient participation in the Outcomes and Registries programme which is developing a device outcome registry to collect information on all procedures involving high-risk devices, such as pacemakers, hip replacements, and breast implants



Autumn 2023

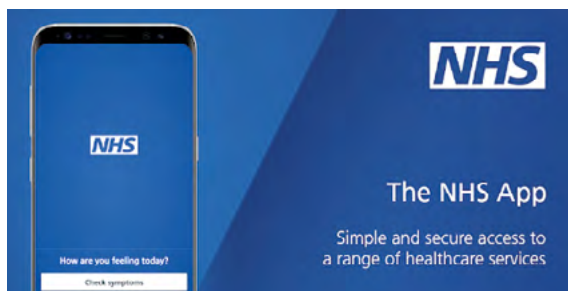
- September saw the PSC playing an important role in the WHO Global Patient Safety Conference in Geneva, chairing a panel on how to make access to safe healthcare a human right and collaborating with patient safety leaders on drafting the WHO's Patient Safety Rights Charter
- in October, following amendments to the Human Medicines Regulations, guidance for dispensing of valproate-

containing medicines in the manufacturer's original pack banned the use of packets without warnings of the risk to the foetus of exposure

in the same month, after raising concerns from patients about psychiatric and sexual side effects of the acne drug isotretinoin, the PSC welcomed new measures to strengthen its safe use

later that month, the PSC ran a series of policy sprints, a means of rapid analysis to address key policy questions, to develop recommendations on implementing Martha's Rule

November saw the introduction of the A-Z of medicines onto the NHS App



in November, the Commissioner 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 – this was accepted in January 2024

the PSC convened the first meeting of a new informal network of patient safety leaders in December



Winter 2023/24

in January, the Commissioner published her updated strategy setting out her ambition and aims for the next year

the Hughes Report on options for redress for those harmed by pelvic mesh and valproate was launched in Parliament in February



The Hughes Report

Options for redress for those harmed by valproate and pelvic mesh

later in February, the PSC joined forces with the Parliamentary and Health Services Ombudsman to call for an overhaul of the complaints process, in a letter to DHSC Permanent Secretary Chris Wormald

later that month, after a call from the PSC to the CEO of NHS England, patient safety was included in the NHS 2024 planning guidance

Following her appointment as an advisor to the MedTech Strategy programme board in September, the PSC helped create a triumvirate of patients, manufacturers and clinicians as the right way of ensuring safety and availability of devices

Spotlights



Redress

The Hughes Report was published on 7 February 2024 and made ten recommendations to the government on redress for those harmed by pelvic mesh and valproate. The recommendations covered both the award of financial redress to patients, as well as non-financial redress in the form of improved access to better designed public services and support.

The PSC produced the Hughes Report after ministers from the Department of Health and Social Care asked her to provide advice on the options for redress for those harmed by pelvic mesh and valproate.

Baroness Cumberlege's *First Do No Harm* review, published in July 2020, recommended the payment of redress but the government previously rejected this recommendation.

The Commissioner was clear to Ministers before she agreed to start this work: the case for redress had already been made by the *First Do No Harm* review and patients must not be subjected to an emotional rollercoaster through the raising of expectations if the government had no intention of providing redress. This second point was important because of the long delays that patients had already experienced after years of campaigning.

Work began in June 2023 and Dr Sonia Macleod, an expert advisor to the *First Do No Harm* review, joined the team as an independent expert.

The project drew from best practice from several existing redress-style schemes already in existence in the UK and internationally



**'I can be the critical friend and provide the constructive challenge'
- Mark Turnball**

Mark Turnball is a Quality and Patient Safety Partner (QPSP) at University Hospital Southampton.

A retired engineer whose wife is a former nurse, Mark is a patient at the hospital. When UHS began piloting the Patient Safety Partner initiative in 2021, he jumped at the opportunity. 'I felt that my background in a safety-related environment would be useful,' he says. 'And throughout my married life, my wife had told me of the horror stories she had witnessed at work.'

Mark's role as a QPSP is extensive. He sits on governance and oversight groups and contributes to improvement projects.

He estimates the role takes up about 35 hours a month on average but this varies considerably. The QPSPs have received positive feedback from the groups of which they are a part as well as from senior leaders – the trust's director of clinical law said they had provided a 'new set of senses'.

'We are seen as positive disrupters and I feel I have changed the outcome of some patient safety investigations,' he says. 'I would recommend the role. But not everyone is suited to dealing with the details of an investigation. You need to be able to be able to look at these cases dispassionately, including where someone has died, but there is support from our allocated mentors and buddies and we also have access to the same support mechanisms as the hospital staff.'

Mark adds: 'It's a great role to get involved with. Staff see that I can say things that they are not comfortable to say – I can be the critical friend and can provide the constructive challenge.'

in healthcare and beyond. As a result, the Hughes Report cites examples from the Thalidomide Trust, vCJD, infected blood, 9/11, and Windrush.

One of the key learnings that emerged from the work was the importance of embedding restorative practice within a redress scheme. This is a process focussed on meeting needs, addressing harm, and restoring trust. Therefore, restorative practice became a key pillar of the Hughes Report and formed part of the first recommendation.

In line with the Commissioner's role, the project team was determined to hear and amplify the voice of patients in the final report. To do this, it conducted interviews with patients, patient representative organisations, and a variety of individuals with professional experience of working with patients who had used pelvic mesh or valproate. An online patient engagement survey ran for six weeks and received over 500 responses from patients. Their responses detailed the impact of the harm they had experienced, along with their views on the form and type of redress they wished to see.

The initial advice went to Ministers in October 2023. The Commissioner also wanted to produce a public-facing document adding further information and patient insights to the advice. This document became the Hughes Report.

In the report, the Commissioner set out proposals for a two-stage financial redress scheme composed of an Interim Scheme and a Main Scheme. The Interim Scheme would pay eligible patients a one-off, fixed sum in recognition of the avoidable harm they had suffered as a result of system-wide healthcare and regulatory failures. On the question of what a suitable amount of money would be for this payment, she highlighted the median amounts that patients had told her via the online survey – £20,000

for mesh and £100,000 for valproate. She also recommended that the Interim Scheme did not introduce further delay and that payments should be made by 2025. The Interim Scheme would be followed by a Main Scheme award, tailored to the individual needs of each patient.

In addition, the Hughes Report sets out the importance of providing those harmed with non-financial redress. The importance of holistic support to repair the harm caused came across strongly from the patient engagement. This

included creating dedicated link worker roles to support patients navigate complex public services, a housing support grant to support home adaptations, and improving the Department for Work and Pensions processes in terms of access to social security benefits. The Hughes Report outlines the need for a new redress agency, independent of government, that patients can trust to implement the proposed redress scheme. In response to questions in Parliament on the day of the report launch, the Prime Minister pledged to consider the recommendations.

The Commissioner suggested that the government respond to the report's ten recommendations within a three-month period following publication.

Three months later the former minister for patient safety provided an initial response saying more work needed to be done before a full response would be forthcoming.

This consideration is ongoing and the PSC awaits a formal response to her report in the summer.





Martha's Rule

Attending the World Patient Safety Movement Summit in California in June, the PSC met Merope Mills, the mother of Martha, who died of sepsis, aged 13, in 2021. Martha had contracted sepsis following a pancreatic injury after a bike accident. Along with her husband Paul, Merope had raised concerns about the deteriorating condition of their daughter but these concerns were not responded to. In 2023, a coroner ruled that Martha would probably have survived had she been moved to intensive care earlier than she was.



Martha's parents called for the introduction of Martha's Rule so patients and families could activate a rapid clinical review in acute settings if their condition, or that of a loved one, deteriorated. Many trusts already have this type of escalation route for healthcare staff, usually provided by a critical care outreach team. Martha's Rule would extend this escalation route to patients and families. It means that patients or relatives can contact a critical care outreach team at any time, day or night, to report any deterioration after informing a nurse on the ward staff.

A similar scheme called Ryan's Rule has been introduced in Australia. In the UK, the scheme is in existence in a handful of trusts, including

the Royal Berkshire NHS Trust, where it is named Call4Concern.

After hearing of Merope's experience, the PSC met with the former health secretary Steve Barclay in August, shortly after the neonatal nurse Lucy Letby was convicted of murdering babies in her care. The PSC raised Martha's Rule and the Secretary of State asked her to lead a series of policy sprints – a way of rapid analysis to address key policy questions – to develop recommendations on how to make the initiative a success across the health system.

The PSC held four policy sprint meetings in October with Martha's parents, the Demos think tank and system leaders, regulators, professional bodies, providers, patient safety experts, the DHSC and NHS England. She then set out Martha's Rule as:

- a structured approach to obtain information relating to a patient's condition directly from patients and their families at least on a daily basis, initially covering all in-patients in acute and specialist trusts
- all staff in those trusts to have 24/7 access to a rapid review from a critical care outreach team who they can contact should they have concerns about a patient
- all patients, their families, carers and advocates also to have access to the same 24/7 rapid review from a critical care outreach team which they can contact via routes advertised around the hospital and more widely if they are worried about a patient's condition.

In February 2024, the former Health Secretary Victoria Atkins announced the rollout of Martha's Rule across England and NHS trusts were invited to join the pilot. The SofS appointed the PSC to chair the Martha's Rule Oversight Group with the DHSC and NHS England. This group brings together Martha's

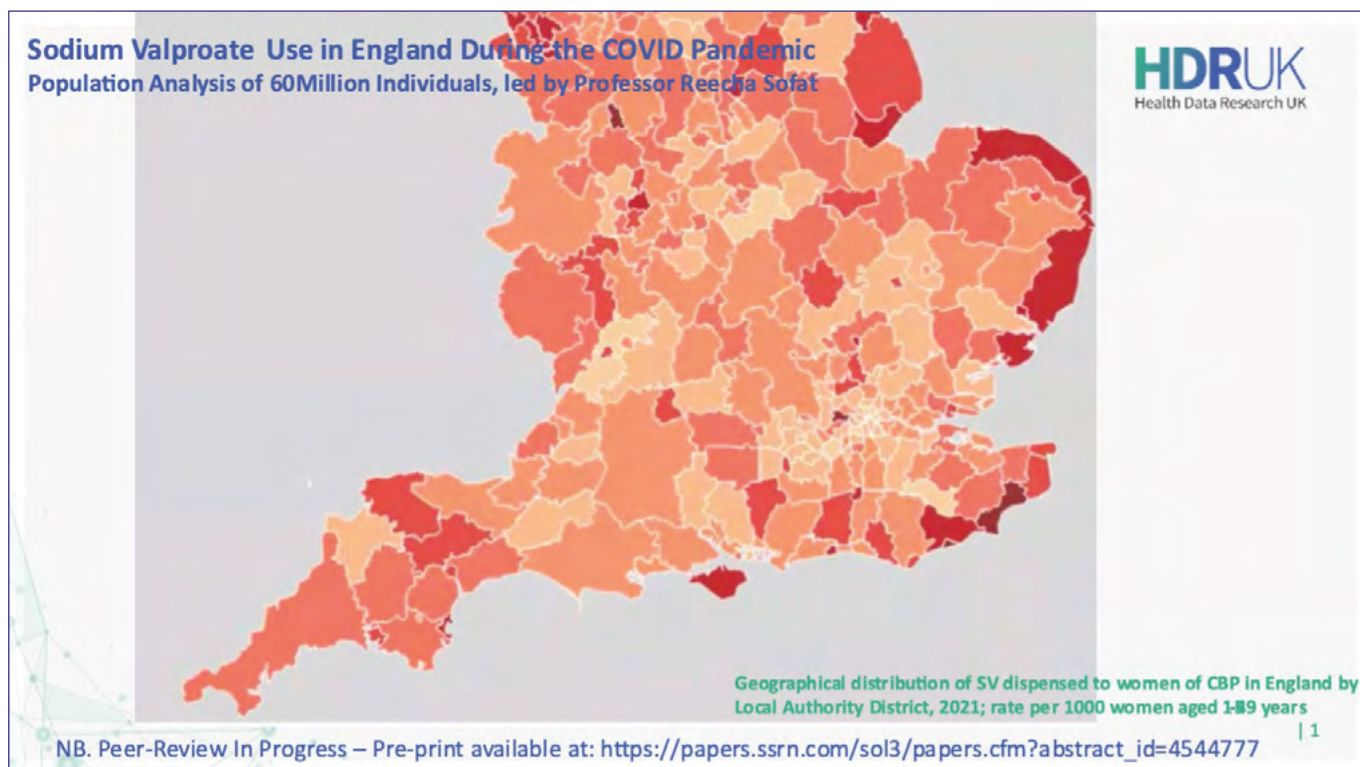
parents, regulators, trusts who have introduced similar initiatives, and professional bodies to oversee implementation.

Valproate

Valproate was one of the Commissioner's three priorities for 2023. She took a comprehensive approach to reducing future harm by limiting the risk to unborn children from women taking the epilepsy medicine valproate and by setting out options for redress to those who had already been exposed and harmed.

During the year, significant steps were taken to improve information to women of childbearing potential taking this potent teratogenic medication. Amendments to the Human Medicines Regulations were introduced to require valproate to be dispensed in original packaging, with the necessary patient information and warning labels.

Further progress was made after the Commissioner recommended that NHS England improve the safe use of the most potential teratogenic medications by monitoring prescribing activity across ICSs. This followed research showing the different levels of prescribing across the country (see map below). In a letter to NHS England Medical Director Professor Sir Stephen Powis, the PSC called on NHSE to set up a National Quality Improvement Programme for ICSs for valproate by September 2024 and then expand it to cover all medication with a pregnancy prevention programme by September 2025. In January 2024, NHSE accepted this recommendation.



Meanwhile throughout the year, patient representative groups continued to campaign for action on redress for those harmed by valproate (and pelvic mesh). And in February, the Commissioner released the Hughes report into redress options (see Redress).

For the patient campaigners, it has been a long journey which has not reached the end point yet. Jo Cozens, chairperson of OACS (Organisation for Anti-Convulsant Syndrome), reflects on the campaign: 'Any progress made means one less baby harmed. But we are bitter. There will be nothing for the older children, some of whom are now in their '50s. And there has been no apology because there has been no action – the report is sitting on a desk in the DHSC.'

Jo has one son, Tomas, who has been diagnosed with fetal valproate neurodevelopmental effects and Aspergers. Despite having a Master's degree, Tomas, who is 24, is like a 15-year-old, according to his mother. 'I worry about the future and what will happen to him when I am not here.'

Emma Friedmann, campaign director of the awareness raising group FACSaware, says she is proud of the progress that has been made. 'The positives are that we have all but got the practice of using valproate during pregnancy banned across Europe,' she says. 'And we have a toolkit on teratogens for patients. Regulatory action has been brought in but there are still gaps in benefits, unfair assessments, and a lack of proper special needs assessment funding.'

Emma, a mother with epilepsy who also took valproate when pregnant, wants to see consumer protection law updated so individuals can sue manufacturers of pharmaceutical products. She welcomed the Hughes report recommendations and now

believes the ball is firmly in the government's court. 'They have the Hughes report – now it is up to them to respond.'

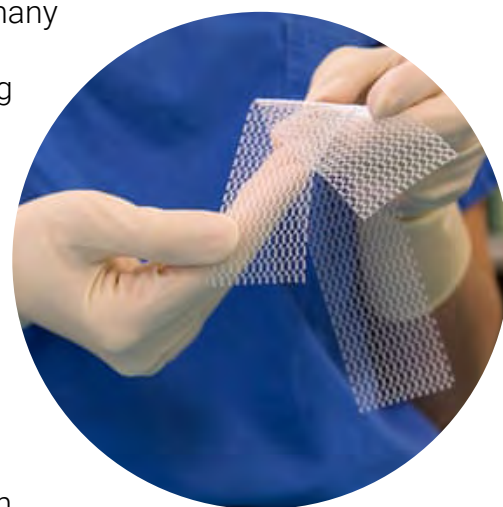
The former minister for patient safety wrote to the PSC on 7 May saying that the work on a response to the Hughes recommendations would take some time and that a full response would be forthcoming in the summer.

Pelvic mesh

Anthony Prudhoe, Head of the Specialised Services Women and Children Programme of Care at NHS England, outlines progress on pelvic mesh.

Pelvic mesh procedures for stress urinary incontinence and vaginal prolapse are currently paused. This move followed the accounts of many women who had been treated using pelvic mesh and experienced severe side effects.

The national pause came into force in July 2018 and was indefinitely extended in March 2019. The pause means that pelvic mesh procedures cannot be reintroduced as a treatment option for stress urinary incontinence until certain criteria have been fulfilled to ensure patient safety and fully informed consent. No decisions will be made about mesh as a treatment option until all of the conditions of the pause have been met and the formal governance steps have been completed by NHS England.



The Women and Children Programme of Care was asked to establish a working group to review the service specification for specialised complex surgery for urinary incontinence and vaginal and uterine prolapse and to consider the evidence for supporting the role of retropubic sub-urethral mesh sling as a treatment option for stress urinary incontinence.

Meanwhile there has been progress to support women who have experienced side effects from mesh and need to have it removed. There are nine NHS hospitals across England providing a regional NHS service for patients with complications of mesh.

NHS England is developing an audit tool and programme for the nine centres in England to provide feedback on the overall patient experience, along with updates about patient activity and referral pattern data.

Arrangements are in place for mesh centres to report back on their programmes for engaging with patients and obtaining feedback from patient and public voice groups.

This feedback will be included in the audit programme report, which will also include information about patient activity, including profiles on patient referrals, referral source, treatment modality profiles, waiting list levels, and waiting times across the pathway as well as an analysis of patient reported outcomes from all the centres.

The audit programme is focused on patient and patient voice feedback but it is not a formal evaluation or research study. The Manchester and UCLH mesh centres have carried out separate evaluations linked to removal outcomes.

In August 2023, the NHS England service specification for patients with complications

of mesh for stress urinary incontinence and vaginal prolapse was revised and extended to include internal and external rectal prolapse. NHS England is working to offer this service as soon as possible.

Yellow Card reporting

In meetings with senior leaders, it was brought to the PSC's attention that there was significant variation in reporting rates between users of different electronic GP systems.

The Commissioner, through her own clinical practice as a GP, noted that there were barriers to reporting

and engaged directly with the system provider. Changes in the design were

agreed which

will improve Yellow Card report visibility and make it easier for primary care staff to raise reports directly to the MHRA. This will be monitored by MHRA once the changes have been implemented.

In the meantime, the PSC continues to promote the Yellow Card at every opportunity while calling for it to be made mandatory for healthcare staff.

In September, the Commissioner proposed that the Yellow Card is placed on the front page of all patient information leaflets.

She has also called for the MHRA to develop a public-facing web page setting out how many Yellow Card reports it receives annually and how it has responded to them.

Her own website's front page provides a direct link to the Yellow Card reporting system.

**Yellow Card**



MedTech strategy

The PSC was appointed as an advisor to the MedTech Strategy programme board where her role has been to ensure that the voice of patients is integral to the programme.

She was influential in the creation of a patient engagement forum, bringing the views of patient groups and charities to the programme board and creating a triumvirate of patients, manufacturers and clinicians. The Commissioner has called for this approach to be taken for all the elements of the MedTech Strategy, in particular the Outcomes and Registries programme. This is creating a mandatory medical device outcome registry to collect information on all procedures involving high-risk devices such as pacemakers, hip replacements, and breast implants, making it easy to recall patients and obtain information about new devices as they are introduced into clinical practice.

The big advances will be seen in this single platform when patient reported outcome measures (PROMs) will be given equal billing to that of clinicians, leading to improved information for patients when they consent to treatment.



Equality and diversity

The Commissioner continued to keep health inequalities high on the agenda, promoting Core20Plus5, raising the issue of variation in valproate prescribing, and of inequalities of health outcomes based on protected characteristics.

In July 2023, the PSC welcomed a critical report from the NHS Race and Health Observatory that demonstrated how certain medical devices do not work properly for neonates from specific ethnic minorities,



'The PSP role can ensure patient safety is at the forefront of all levels of care' - Sylvie Buckingham

Sylvie Buckingham is a Patient Safety Partner at Oxford University Hospitals. 'My background has been in both healthcare and education and as a staff nurse, rising to Head of Nursing, I felt I had some of the skills required, plus an insight into healthcare.'

Sylvie meets regularly with the consultant lead for patient safety and the Head of Patient Experience to set out what they hope to achieve and to reflect on her observations.

'These meetings are invaluable to ensure I am doing the right thing,' she notes.

Sylvie receives ongoing advice as to who to talk to and what meetings to attend. Often these conversations provide a new perspective on how care is being managed and Sylvie says this has led to actions for improvement.

'I have been very pleasantly surprised at the way I have been included by the Trust in all aspects of care, from interviewing for staff to attending events and Board meetings,' she reflects.

Sylvie believes that her views on patient issues are listened to and where necessary, acted upon. The fact that she has insight into the way healthcare has developed has been useful but she believes that a critical eye is more important.

She says: 'My role is voluntary and I feel that is an advantage as I do not have any allegiance to the Trust, so am not biased.'

'The role of PSP is new and it is evolving,' she adds. 'And It can ensure patient safety is at the forefront of all levels of care. Isn't that what we all hope for?'

particularly when monitoring oxygen blood levels to diagnose cyanosis or jaundice. She will continue to highlight the risk of health inequalities in medicines and medical devices as part of the pledge she made following this report.

March 2024 saw the publication of Dame Margaret Whitehead's review of equity in medical devices, which the PSC welcomed, specifically its recommendation that the health sector take a system-wide approach to reducing health inequity. The review found that potential bias could be introduced at every stage of the medical device lifecycle, from the original concept through design and development to testing and eventual deployment in the NHS.

It also found extensive evidence of poorer performance of pulse oximeters for patients with darker skin tones. These devices over-estimate true oxygen levels to a greater extent than in those with lighter skin. Evidence of harm stemming from this poorer performance has been found in the US where there is a strong association between racial bias in performance of pulse oximeters and delayed recognition of disease, denied or delayed treatment, and worse, organ failure and death in black patients compared with white patients.

The review did not find any evidence from studies in the NHS of this differential performance affecting care but said the potential for harm was clearly present.



It recommended mitigation measures to ensure existing pulse oximeters can perform to a high standard for all patient groups to avoid inequalities in health outcomes.

Patient information

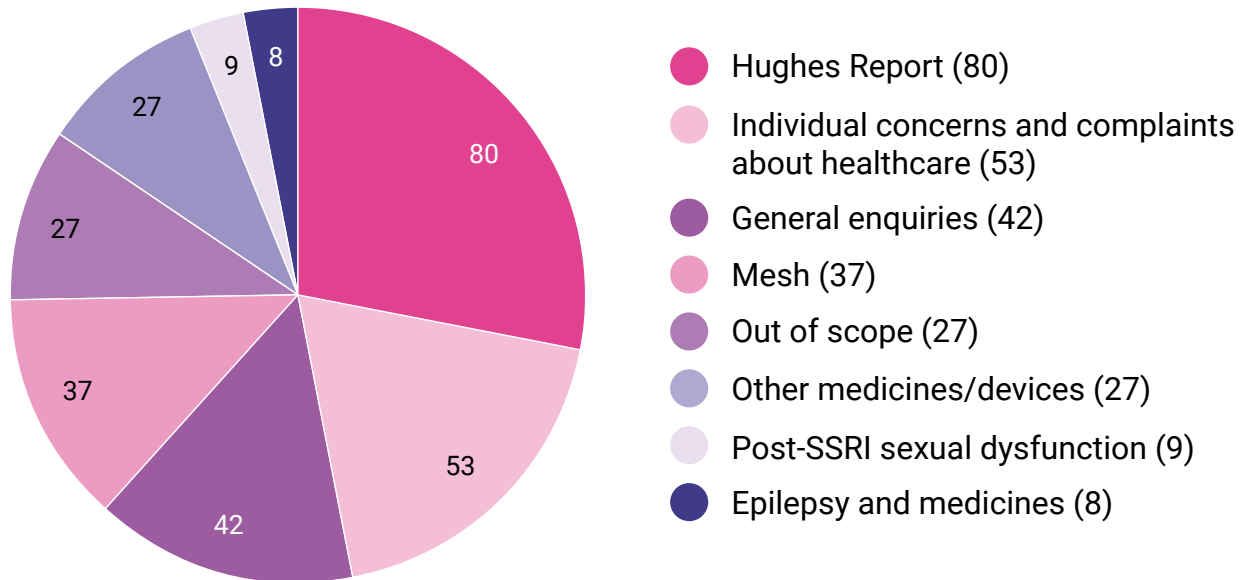
In May, the PSC was appointed to the ePI taskforce which brings together NHS organisations with the medicines regulator and medicines manufacturers to facilitate digital-first medicines information for patients and ensure nobody is left behind.



As a member of the taskforce, the Commissioner is keen to see the digitalisation of patient leaflets so they become available in multiple formats to support patients with accessibility needs, increasing their knowledge about their medicines and enabling them to be partners in their care, as well as voice technology for those with sight loss.

In November, following the intervention of the PSC, the redesigned NHS App incorporated the A-Z of medicines, providing patients with access to a wealth of information on the move. Further expansion of the app is planned so that people with additional needs are not left out of the healthcare information revolution.

Correspondence



In the year to April 2024, the level of correspondence to the PSC rose compared with the previous year. Much of it related to the Hughes report into redress options for those harmed by valproate and pelvic mesh and were received after the report's publication in February 2024.

A high volume of correspondence was from people raising specific concerns and complaints about the care or treatment they, or a loved one, had experienced, often asking the Commissioner to intervene in their case.

General enquiries were broad-ranging and included queries about the Advisory Group, Martha's Rule, questions about the Commissioner's work, and offers of support. Of the remaining specific subjects raised, the PSC received correspondence about post-SSRI sexual dysfunction and Covid-19. Other topics raised included cosmetic surgery, fluoroquinolones, hysteroscopy, and topical steroid withdrawal.

The OPSC is grateful to the many patients who have made contact, enabling the PSC to amplify patient voices to the right part of the system to ensure patients are kept safe. Patients who contacted the OPSC about areas that are outside the scope of the PSC were signposted to the part of the healthcare system that could address their questions. This highlights the complexity of the healthcare system that patients and families have to navigate.

Patient safety was included in the 2024 planning guidance for the NHS after the PSC wrote to the NHS chief executive following discussions with senior trust leaders

Finance

While the OPSC's operational line of responsibility runs to the Health and Social Care Select Committee, its financial responsibility and requirement to manage public money effectively runs via 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 for 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.

Business Plan 2024-5

The business plan for 2024-5 sets out the strategic priorities and activities of the Patient Safety Commissioner and her office in line with her statutory responsibility under the Commissioner for Patient Safety (Appointment and Operation) (England) Regulations 2022.


The Commissioner published an updated strategy in January 2024 with three strategic priorities. These will be supported by four strategic projects:

- The Principles of Better Patient Safety
- The Patient Safety Atlas of Powers
- A collaborative project on accessibility barriers to safe healthcare in relation to medicines and medical devices for patients with sensory impairments
- A report on closed loop medicines administration and the barriers to implementation.


The primary activity for the year will be delivery of the public consultation on the Principles of Better Patient Safety, as previously referenced in the Business Plan for FY23/24 but delayed due to resourcing constraints. This work is a statutory requirement of the Commissioner.

The PSC will develop a Patient Safety Atlas of Powers, setting out the powers and remits of the key patient safety organisations working in England. She will also analyse closed loop medicines systems outlining their benefit to patient safety and deliver a collaborative project with patients with accessibility needs on medicines and medical devices patient safety.

Over the coming year, the PSC will continue to receive correspondence from patients and patient safety experts and engage with the healthcare system about the benefits of listening to patients and the need to develop a just and learning culture. She will provide responses to inquiries and ministerial requests, provide evidence to relevant inquiries and the health select committee, and make recommendations to healthcare organisations to improve patient safety, as well as contributing to public consultations.



In November, the PSC committed to highlighting bias in medical devices and raised this issue with the MedTech Strategy programme board as part of the NHS Race and Health Observatory World Café conversation



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