Patient Safety Commissioner

100 Days Report

Introduction

Dr Henrietta Hughes OBE FRCGP
Patient Safety Commissioner

The Cumberlege report, *First Do No Harm* (*FDNH*), showed that patients did not feel heard, did not have the information needed to make the right decision about their care, could not trust the answers or that the system prioritised their and their family's safety.

As the first Patient Safety Commissioner for England, I have been listening hard to the voices of patients and their representatives to put this right. I would like to thank everyone who has been so supportive and helpful and especially to the campaigners and people who have kept this in the spotlight. I am especially grateful to the Patients Association for kindly publishing this report on their website.

My role is to promote the safety of medicines and medical devices, to promote the voices and views of patients and the public and to help the government and the health system to listen and act.

This report sets out what I have heard in my first 100 days, what I have done and my priorities for the year ahead.

Over my first 100 days in the role, I have heard a yearning desire for patient safety to be at the top of the agenda. I've heard this from patients, healthcare professionals and senior leaders. It is clear from what they told me that the focus of the health service is on productivity, operational performance, and financial control. Medicine is industrialised when it needs to be humanised. As well as asking 'What's the matter with you?' we should be asking 'What matters to you?' so that healthcare is personal, meaningful, and safer.

In the Department of Health and Social Care's (DHSC) most recent outcome delivery plan (2021-2022), the word 'safety' is mentioned twice in relation to maternity services, but not at all in relation to medicines, medical devices, or other aspects of patient care.

Neither DHSC nor NHS England have a patient representative on their Boards or hear a patient story at Board.

And when people try to raise their concerns, recent reports from the CQC and the National Guardian's Office present a worrying picture - patients feel less likely to be heard and leaders are less likely to listen to workers. It is clear that the culture is getting worse and unless leaders set 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.

I have heard from patients and their families that the concerns described in *First Do No Harm* more than two years ago continue. There are still, on average, three babies a month born after exposure to sodium valproate. This is a scandal bigger than Thalidomide, with an estimated 20,000 children exposed to the drug with physical deformities and learning disabilities whose needs are not being met. This is not because of inaction, it is because health leaders don't understand the health system, don't own the problem, and don't always work effectively together, leaving patients to pick up the pieces.

I have heard about problems with pelvic mesh. That patients suffering pain and disability are still not being heard, not being referred to specialist pelvic mesh centres, or experience long waits and patchy provision of services. I have heard about the problems for families affected by hormone pregnancy tests, cut out of conversations due to ongoing litigation and not having their voices heard.

I have heard about a lack of respect, a lack of information and registries so patients can't meaningfully consent to treatment, a lack of transparency around payments to clinicians and conflicts of interest, and a lack of commitment to offer financial redress to people where regulation has failed.

'Commitment to patient partnership'

The Patients Association was pleased when the Government created the position of Patient Safety Commissioner for England. We were even more pleased when Dr Henrietta Hughes was appointed as the first Commissioner. We know she has a commitment not just to patient safety but also to patient partnership. For us, patient partnership is a fundamental part of improving patient safety and the fact this is part of the Commissioner's job description, is excellent news for patients.

We supported the role of Commissioner when it was recommended in First Do No Harm in 2020. The details of patients' experiences catalogued in that report were appalling. And while most patients receive safe care in the NHS, it is obvious to us that a failure to listen to patients leads to harm and features in every independent enquiry into NHS failings.

This failure to listen to patients and carers is part of a culture prevalent in the NHS. This is something we know Dr Hughes agrees is an issue and has pledged to tackle. We are fully supportive of this goal and welcome her aim of creating a listening environment where people are genuinely interested in patient feedback and staff are empowered to act on that feedback. We hope Dr Hughes will be able to support NHS leaders to transform the NHS into a listening organisation that is willing to partner with patients. We further hope the NHS can become better at learning from excellent practice elsewhere in the system - too often good work does not seem to travel well across the NHS.

Her focus on psychological safety is important too: this is vital for both patients and staff. Too often we hear from and about patients who have voiced concerns and found them dismissed. This is not acceptable. Both patients and members of staff who raise concerns should be listened to and their concerns acted on. We will support Dr Hughes's efforts in any way we can.

Rachel Power
Chief Executive, Patients Association


First Do No Harm

The report of the Independent Medicines and Medical Devices Safety Review

I have also heard from people with concerns about a much wider range of problems. For example, devastating losses from suicide after taking isotretinoin, a treatment for severe acne. From patients who have had catastrophic side effects from medicines such as fluroquinolones, topical steroid treatment, antidepressants, prescribed benzodiazepines, and painkillers. Concerns about the Yellow Card reporting system, the Covid-19 vaccine damage redress system, the timing of medicines administration, supply chain issues around syringe drivers, and the regulation of electroconsulsive therapy.

As a GP I know that the lack of progress with digital systems means that we are working in error-provoking environments, with 237 million medication errors each year in the NHS. The drivers for digital transformation are productivity and cost when the overwhelming driver should be the benefits to patient safety.

I have met with patients, campaigners and representatives including parliamentarians who have helped to amplify patients' voices. I have also seen the green shoots of progress, meeting Patient Safety Partners and hearing about how they are helping to improve patient pathways, incident and complaints processes, and bringing the voices of patients to Boards. I have seen tracking systems that improve patient safety and examples of where listening and responding improves safety and satisfaction for patients and staff. But these are not happening everywhere.

If you are a patient or a service user, know that I am listening to you and will promote your safety in relation to medicines and devices and amplify your voices, views, and experience. I will work to embed patient voice and listening to patients and families into every part of the design and delivery of healthcare. The views and voices of all patients matter, and I will endeavour to ensure that all patients are included.

'One straightforward way to connect with the NHS'

Significant improvements have been made in patient safety over the last two decades. But we know there is more to do, and always will be.

As Baroness Cumberlege set out in her review recommending the appointment of a Patient Safety Commissioner, too often we have found the voice of the patient is not properly heard.

Considerable work in the NHS - together with extensive contributions from patients and clinicians - has helped us create more and more ways for patients and their families to connect with services and provide feedback.

The appointment of Dr Hughes as the first Patient Safety Commissioner is an opportunity to ensure these various mechanisms are brought together, providing patients and families with one accessible and straightforward way to connect with the NHS.

Henrietta's appointment builds on the foundations set out in the NHS Patient Safety Strategy and allows us to ensure the lived experience of patients is continually being used - alongside ever more rigorous and comprehensive data - to improve care, and we look forward to continuing this important work together.

Amanda Pritchard
CEO, NHS England

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. In essence, everything we do as a healthcare system because everything we do is about patients.

Everyone reading this has a part to play in delivering safe care - know that you can make a difference by putting safety at the top of your agenda as they do at Hounslow and Richmond Community Healthcare NHS Trust Board meetings. Introduce patient voices into your governance, in your Board meetings, commissioning and contracts meetings, design of strategies, policies and processes, team meeting agendas, annual objectives, appraisals, reviews of complaints and incidents, inspections, and reward and recognition.

I want us to be able to look back in astonishment on the way that we operate now. This is the moment to set a new course with supported 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 system is not good enough at spotting trends in practice and outcomes that give rise to safety concerns. Listening to patients is pivotal to that. This is why one of our principal recommendations is the appointment of an independent Patient Safety Commissioner, a person of standing who sits outside the healthcare system, accountable to Parliament through the Health and Social Care Select Committee. The Commissioner would be the patients' port of call, listener, and advocate, who holds the system to account, monitors trends, encourages, and requires the system to act. This person would be the golden thread, tying the disjointed system together in the interests of those who matter most.’
>
> **Baroness Julia Cumberlege**
> Introduction to *First Do No Harm*,
> the Independent Medicines and Medical
> Devices Safety Review report 2020

What I have done

During my first three months as Patient Safety Commissioner, I have met patients, healthcare staff, patient safety specialists, and healthcare providers. They have told me about the way in which the system fails to enable them to put patient voice at the centre of what they do.

I have:

- spoken to people who have been harmed by pelvic mesh or whose families have suffered because of the use of sodium valproate or pregnancy hormone drugs and are campaigning for redress
- met with patient safety partners, the patients providing challenge and insights to NHS trusts, Integrated Care Systems and regions
- had discussions with regulators, healthcare providers, manufacturers, patient safety specialists and patient groups
- raised issues with ministers, MPs, NHS leaders, royal colleges, and educators, developing a network of influence to put patient safety at the heart of the health ecosystem including independent providers
- presented to key patient safety conferences, including:
    - the HSJ Patient Safety Congress
    - the Professional Standards Authority 'Safer Care for all' conference
    - the Safer Healthcare and Biosafety Network conference
    - the Patients Association patient participation week.

I have heard about the problems with the NHS supply chain and the impact it has on patient safety. I have raised concerns about isotretinoin and met with families who have lost loved ones to suicide and or experienced life changing side effects from this drug.

From the correspondence I have received and the conversations I have had, it is clear the challenge goes far wider than the three interventions outlined in the *FDNH* Review.

Meeting expert patient Jono Broad

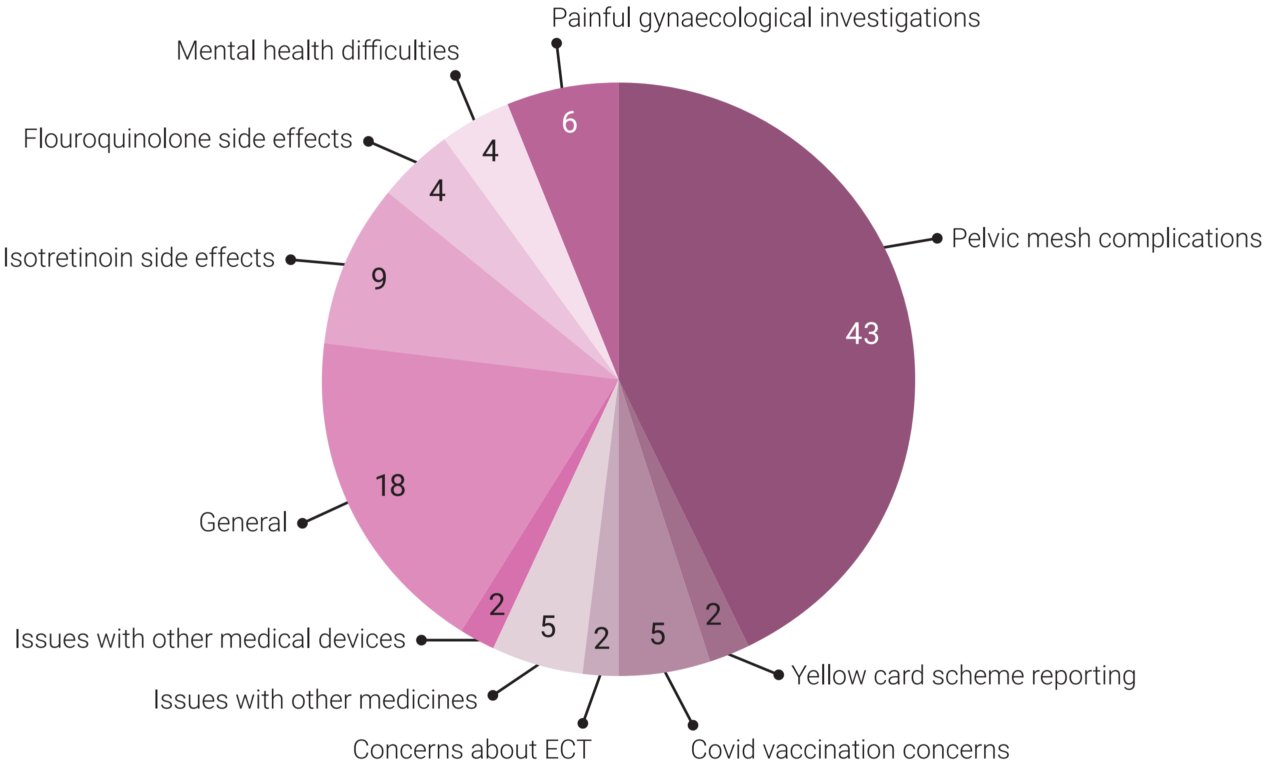
Over the past three months, I have recruited a set-up team and we are developing the governance structure including an advisory group. We are also developing and agreeing Memorandums of Understanding (MoUs) with relevant organisations and joint objectives. We are planning a public consultation on the Principles of Better Patient Safety.

I have received correspondence from patients who have been concerned about harm by either medicines or medical devices and have responded directly to them or signposted them to organisations who can help.

This chart sets out the issues that have been raised through direct correspondence with my office and gives a snapshot of the breadth of concerns that patients have raised. This information helps me to escalate concerns to those who can influence change.

The first 100 Correspondents

Over 120 correspondents have raised matters with me, details of the first 100 are in this chart:



‘Getting it right for patients’

One of my visits was to University Hospitals Southampton NHS Trust which has combined its patient safety partners programme with its quality improvement programme, creating Quality and Patient Safety Partners (QPSPs). These six volunteers come from a range of backgrounds and provide a unique insight into the work of the trust. They have undertaken the same patient safety training as staff and can access a mentor to support them in their work. For one, Linda Taylor, the trust listens to their views and trusts them. ‘It works because we all have the same aim - getting it right for patients.’

The QPSPs point to their work on the multiple sclerosis workstream where their input into the understanding of the patient pathway is much more than just when patients enter and leave the hospital. It includes acting on early issues to reduce the chance of being admitted to hospital while helping patients to manage their condition at home after treatment.

Their next focus is on recruiting new QPSPs and ensuring they reflect the make-up of the trust’s users, including its diverse population. They are also continuing their work as part of a patient safety partners network and are supporting other NHS trusts in developing similar programmes to put patient voice centre stage.

Achievements

In my first three months I have:

- listened to patients and flagged their patient safety concerns to the heart of government
- raised concerns to the General Pharmaceutical Council who wrote the next day to 91k pharmacists to avoid dispensing sodium valproate in white boxes without warnings that patients must be on the pregnancy prevention programme
- engaged with patient groups and healthcare professionals to develop co-produced resources for patients with side effects following pelvic mesh surgery
- influenced the decision by NHS England and the Pharmaceutical Services Negotiating Committee to focus on sodium valproate prescribing in their 2023 community pharmacy audit
- challenged NHS England to include patient voices in the design and language of specialised services national specifications
- engaged with health leaders across the patient pathway to improve the safety of sodium valproate prescribing to patients with childbearing potential
- raised issues about redress that patient groups have mentioned with the relevant minister, and she has asked me to review this issue
- encouraged regulators to streamline information about the pregnancy prevention programme for patients taking sodium valproate.

What I have heard

Pelvic mesh

According to NHS Digital it is estimated that around 100,000 people, mostly women, have had surgery using pelvic mesh for stress urinary incontinence and pelvic organ prolapse over the past 20 years.

It is estimated that up to 10% of patients have had severe long-term problems following the use of pelvic mesh due to scarring, risk of infection, damage to nerves and sensitive tissues amongst other complications.

Mesh-injured patients can suffer extreme pain and disability which impacts on their ability to work. Some have lost their jobs, their homes and their relationships, including sexual relationships. Following surgery, patients were not asked about their experience of pain, burning, or pain on intercourse for themselves or their partner - only 'are you dry?' as a marker for whether the treatment was successful. Patients, describe dismissive attitudes and degrading treatment from healthcare professionals. I have been absolutely shocked by what I have heard. I ask myself whether we would have the same approach if predominantly male patients were being treated.

According to the campaign group, Sling the Mesh, 6 in 10 surgeons do not report problems when these occur, so it is difficult to know precisely how many patients are affected. GPs may not be aware of problems with pelvic mesh, or about the national mesh removal centres set up in 2021.

'Mesh made me stand up and fight for others'

Kath Sansom had a pelvic mesh inserted in 2015 after developing stress urinary incontinence following childbirth. Immediately she began to feel extreme pain: 'It was dreadful, like someone had taken a baseball bat to my legs and hips, with an awful burning inside.' She had the mesh removed seven months later but has been left with autoimmune diseases and allergies.

'I regret that I let it happen,' she says. 'I felt stupid and embarrassed that, like all of us, I did not research it before I went in - I trusted my doctor and wasn't warned of the risks.'

In June 2015 Kath founded Sling the Mesh, the patient campaign group, which now has over 10,000 members. 'Mesh has taken away the quality of life from thousands of people globally. People have lost jobs, marriages, their health. Nobody took the mesh-injured seriously until I kept pushing out the message in press releases, stories, blogs, social media.'

Kath's campaign led to a plethora of media coverage and support from politicians, then the *First Do No Harm* Report from Baroness Cumberlege, followed by the establishment of the Patient Safety Commissioner role.

'For me the aim is to make sure it doesn't happen again,' says Kath. She wants to see a Sunshine Act implemented to reveal payments made by manufacturers to doctors that can lead to biased healthcare evidence. She also wants to see mandatory reporting by doctors of any complications through the Yellow Card scheme, pointing out that two thirds of mesh complications ware not being logged. Robust medical device approval, fully informed consent, and non-invasive preventative measures, such as physiotherapy, are also key.

Kath welcomes the appointment of the Patient Safety Commissioner: 'I hope she has the courage to challenge and champion.'

And even if patients are referred, the waits for appointments are long, travel is expensive and time consuming. The centres do not all have the holistic wraparound care recommended in the *FDNH* report. Mesh-injured patients are unable to attend the centre of their choice and most distressingly, may face the same surgeon who inserted the mesh.

Despite everything in *FDNH* about including and involving patients, I lack confidence that the national specification for mesh removal centres was developed with the involvement of patients harmed by mesh.

In 2018 there was a national pause in the use of mesh in England for stress urinary incontinence. An oversight group was set up and recommended improvements in the way that complications were managed. In December 2022, the government announced that it would look at the number of deaths where complications of pelvic mesh were a factor.

While removal centres do their work, we need better information for affected patients and GPs about potential complications and details of all of those who have had mesh implanted must be included in a national registry which requires all surgeons to input the data.

Sodium valproate

We know that sodium valproate is an effective treatment for epilepsy and some mental health conditions. But it is potentially harmful to a developing fetus and can lead to physical deformities and learning difficulties in children if taken when the woman is pregnant, known as Fetal Valproate Syndrome.

There is increasing evidence that children of men taking valproate are affected and that there are intergenerational effects. It has also been cited as a contributory cause of death.

The PSC meets Emma Murphy and Janet Williams from IN-FACT (the Independent Fetal Anti-Convulsant Trust)

Following the campaigning work of Emma Murphy and Janet Williams MBE, requirements were introduced for women of childbearing age with epilepsy to:

- be on a pregnancy prevention programme when taking valproate
- have an annual review by a specialist prescriber
- be informed of the risk to children of the medicine
- be using highly effective contraception.

And clear warning labels were to be on all boxes of valproate tablets.

This sounds good in theory. But the practice is different: the 2019 community pharmacy audit showed that almost one in five had not seen their GP or specialist in the last 12 months to discuss valproate use and the need for appropriate contraception. Pharmacists were not referring or signposting a sizeable minority who appeared not to have appropriate contraception back to the prescriber. Furthermore, 11.1% of patients did not receive the required patient warning card.

There is poor communication between healthcare providers and information systems do not support patients to receive follow up appointments and so can become lost in the system.

The manufacturer has warning labels and a card on their packaging. But when it comes to prescribing, if a GP prescribes the standard multiples of 28 tablets, while the pack sizes are 30, 100 and 112 tablets, under current legislation the pharmacist has to split the pack and use a plain white box.

The *FDNH* review report estimated that hundreds of babies a year were still being born exposed to sodium valproate - a drug which is so potentially harmful during pregnancy that if you are taking it, you must not donate blood.

The PSC with Emma Murphy and Janet Williams at the HSJ Patient Safety Congress

And we do not know how many women choose a termination when they first find out about the risks when pregnant. The current protections also don't help women who would love to have a family but are fearful of coming off contraception in case they harm their baby.

'I got fobbed off. I was told I was reading into things'

For Emma Murphy, who founded In-FACT (the Independent Fetal Anti-Convulsant Trust) valproate is a scandal. As she told the Commons Health and Social Care Select Committee in December, 'there's too many affected children and adults who were told they were bored housewives'.

Emma has six children, five of whom have disabilities, including autism and developmental delay, because of taking an epilepsy drug while pregnant.

When diagnosed with epilepsy at the age of 12, Emma was prescribed valproate, regarded as the best drug, to manage her seizures. When pregnant with her first child, she asked her GP and her neurologist whether it was safe to continue using valproate and was reassured that it was.

Throughout her following five pregnancies at every hospital appointment, she continued to ask about the safety of the medication during pregnancy. 'When I raised worries, I got fobbed off: I was told I was depressed; I was told I was reading into things.'

When she conceived her sixth child, she was prescribed another anti-convulsant drug, Keppra, and her seizures became more frequent but milder. He was born without FVS but has kidney issues.

In 2012 she joined forces with Janet Williams, who had already been campaigning on behalf of those with Fetal Valproate Syndrome (FVS), and formed IN-FACT (The Independent Foetal Anti-Convulsant Trust) to represent the estimated 20,000 people with FVS. An All-Party Parliamentary Group for valproate and other anti-epilepsy drugs was set up and in 2018 regulations were strengthened so that valproate medicines cannot be used in women of childbearing potential unless a Pregnancy Prevention Programme is in place.

But more needs to be done. 'It's truly scandalous - women are not told about the risks. We still see valproate dispensed in white boxes without warnings. Women are not systematically signing forms stating they have received the information to make an informed choice.'

Emma wants to see redress and compensation for the thousands of people that have been affected. 'There needs to be an apology on behalf of the government - not just the NHS - because regulators and the government knew about the risks.' Emma welcomes the new Patient Safety Commissioner: 'She's needed, she's sympathetic, she's positive, she's present.'

With Rosie Benneyworth, interim Chief Investigator, Healthcare Safety Investigation Branch

No one individual or organisation is at fault - it is a lack of system thinking, a lack of professional curiosity on the part of regulators who may not understand the commissioning system. Contraception services are commissioned by local authorities. General Practice, community pharmacy, neurology and mental health clinics are commissioned by Integrated Care Systems. GPs medicolegally cannot prescribe sodium valproate without an annual review by a specialist prescriber. But patients may be left to follow up from secondary care and lack of communication risks unintended pregnancy.

What's the alternative? GPs have no option but to prescribe because without the medication patients may have a life-threatening seizure. Patients face a postcode lottery to access services and the information they need to make the right decisions about their care.

MHRA have recently announced that due to concerns about the children of men taking sodium valproate and the possible intergenerational effects, stricter controls will be put in place.

The MHRA has advised that no one under the age of 55 should be initiated on valproate unless two specialists independently consider and document that there is no other effective or tolerated treatment. Where possible, existing patients should be switched to another treatment unless two specialists independently consider and document that there is no other effective or tolerated treatment or the risks do not apply. No patients should stop taking sodium valproate without first talking to their healthcare professional.

I welcome these stricter controls, but remain concerned that the complexity of the healthcare system still leaves patients at risk of future harm.

Primodos

Oral hormone pregnancy tests (HPTs) such as Primodos, containing ethinylestradiol and very high doses of norethisterone, were given to over a million women across the world from 1958 to 1978, when the test was withdrawn from the market because of concerns about birth defects, including spina bifida, brain and heart problems, and deformed limbs.

One Marie Lyon, who founded the Association for Children Damaged by Hormone Pregnancy Tests (ACDHPT), used the Primodos test to confirm she was pregnant. Her daughter was later born with a birth defect.

'Due to taking Primodos on the advice of my GP I have spent 52 years either wondering what caused my daughter to be born without a hand or lower arm and whether it was my fault, then fighting to expose the truth about how these high dosage untested and unnecessary synthetic drugs affected our unborn children,' she says. 'I was lucky as my daughter survived but many mothers suffered stillbirths and infant deaths. This fight for justice has taken over my life, but I will not stop until our families gain justice for their children by exposing the documented evidence of the harm they caused. We owe it to all young women today to ensure any drugs used during pregnancy are safe.'

The *FDNH* review of 2022 found that the test should have been withdrawn in 1967 when concerns were first raised in a medical journal about a link between HPTs and birth defects.

The ACDHPT continues its campaign for redress. A court case is pending and a case management conference is scheduled for May which will determine further action.

Green shoots

I have also seen many examples of excellent patient safety policy and practice:

- the Scan 4 Safety initiative in action, improving safety and saving money but with very limited extension beyond the initial six pilot trusts
- NHS Resolution's work on consent including resources for staff
- the work of data analysts using artificial intelligence and patient feedback platforms and analyse patient data from a range of sources including social media and internal patient comments so issues can be identified early.

I also welcome the National Patient Safety Strategy which has provided guidance on engaging patients to families after incidents occur and the Patient Safety Incident Reporting Framework (PSIRF) new way of looking at incidents to ensure that patients' voices are included. The Healthcare Safety Investigations Branch (HSIB) has transformed the way in which inspectors engage with families and include people from a wide range of backgrounds, strengthening its diversity.

What needs to happen

From my many discussions I have identified what is needed to champion patient voice and reduce incidents of avoidable harm:

- patient voice to be included in all aspects of the design and delivery of healthcare
- patient access to information and data
- a psychologically safe culture
- a swift, compassionate response when things go wrong.

The National State of Patient Safety report published by the Institute of Global Health Innovation in December states that feelings of psychological safety in hospital can be helped, or hindered, by the quality of communication from clinicians. But patients are still not being heard or getting the information they need, and the dismissive and defensive behaviours continue. When people voice inconvenient truths, the system turns its back and fails to listen and act. The white box consultation and isotretinoin review have been delayed due to political upheaval. Healthcare professionals are not required to use the Yellow Card system to raise safety concerns to MHRA. Patients say that efforts to listen and engage are tokenistic and a tick box exercise.

I want to see patient safety as the top of Boards' agendas, patient voices heard by Boards and a psychologically safe culture created in organisations, using visible leadership, communication, and engagement, which all impact positively on staff too.

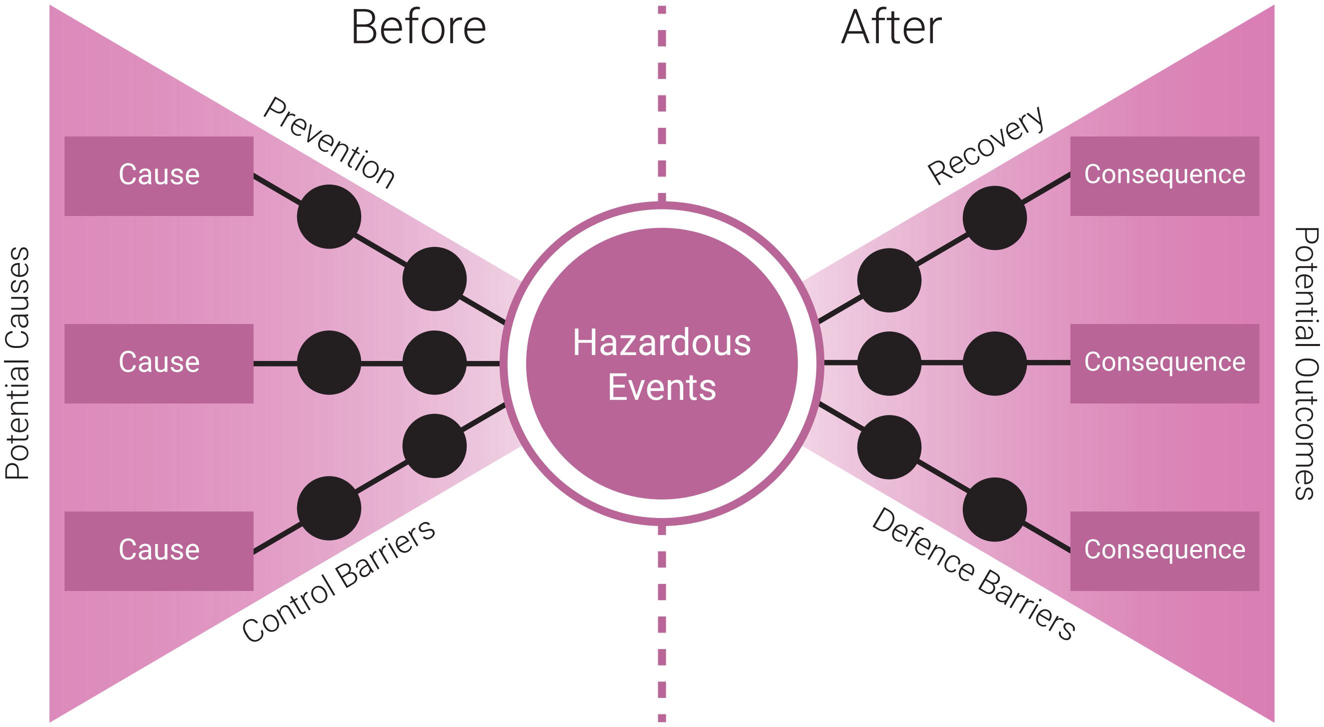
We need to ensure that we are obtaining feedback from all patients, including those whose voices are seldom heard. That's why diversity on Boards is so important to open our eyes to the reality of experiences from diverse patient groups. Inclusivity must run through everything we do: the patient voices we seek need to come from every part of our communities, from people with disabilities, people for whom English is not their first language, and people from disadvantaged communities.

Leaders also need to look at how we share and monitor information about issues across Integrated Care Systems and nationally, through professional groups and social media to detect early signals of harm. For example, electronic prescribing systems in hospitals don't link to GP prescribing or electronic systems in community pharmacy. So clinicians don't have the full picture and data has to be entered in again and again, increasing errors and risking harm.

Meeting Maria Caulfield, the minister for mental health and the women's health strategy

High safety industries design safety in from the start: they ask what is the hazardous event, what could prevent it from happening, what the consequences are, and what can mitigate them.

In health we focus too much on the consequences, looking backwards at what has gone wrong. We need leaders to stop harm in advance, identifying and managing the causes and the controls. The healthcare ecosystem is made up of complex interconnected systems which means actions taken in one area have consequences elsewhere. Assumptions are made and a learned helplessness develops, with patients and staff disempowered and worse. We need to borrow from Process Safety Management, with leaders committing to putting patient safety first, identifying the causes, the controls and thereby reducing harm to patients.



Bow tie diagram used in Process Safety Management Systems

What I will do

My top three priorities are

- Culture change
- Pelvic mesh complications
- Sodium valproate

My plan is

On culture change, to:

- hold a public consultation on the Principles of Better Patient Safety for the Patient Safety Commissioner
- work with healthcare leaders to put patient voice at the core of their activity and reporting
- amplify patients' voices in all parts of the health system to ensure they are heard
- identify and highlight where patient voice is neglected
- challenge organisations to identify a named patient voice on all Boards and to place patient stories at the top of their meeting agendas
- campaign to improve the use of Yellow Card reporting
- campaign to see the NHS number used as the default and unique identifier
- work to ensure patients are engaged in the development of all national specifications
- develop the Patient Safety Commissioner website as a hub of best practice in championing patient voice
- work with policy teams to improve conflict of interest declarations
- support the professions to improve consent and supported decision-making
- hold the government to account for financial redress for all harmed patients and families identified in *FDNH*

On pelvic mesh, to:

- co-produce resources for patients and GPs about side effects from pelvic mesh surgery
- work with NHS England to provide patients choice of access to specialist mesh centres
- work with the health system to ensure that information is available to all patients on national registries

On sodium valproate, to:

- support the health system to include the views of all stakeholders including patients to reduce harm from sodium valproate to the lowest possible level
- work with health leaders to ensure that all relevant patients are on a Pregnancy Prevention Plan (PPP) and given the necessary information
- collaborate with partners to ensure annual reviews are carried out by specialist prescribers

- work with partners across health to eliminate dispensing of sodium valproate in unlabelled white boxes
- work with professional regulators to streamline the advice to their registrants on sodium valproate and contraception
- raise patient awareness through charity collaboration.

With the help of patients, their families, and representatives and with people from across the health system, I am on a learning journey. I'm hearing about the worst examples of dismissive attitudes and best examples of compassionate care, of leadership, and of a system that is on the brink of change.

My term is three years - a short time to transform the attitudes, behaviours, and culture of the largest employer in the country and a system under enormous pressure. My remit is for the safety of medicines and medical devices, but getting it right for medicines and medical devices reads across to all aspects of interacting with patients and families.

There is no time to lose to change the focus onto listening and acting on feedback from patients and families. This is a legacy that health leaders can embrace, or neglect with the inevitable consequences of harm.

I want national bodies, regulators, professional bodies, frontline staff, and patient groups to step forward and demonstrate their commitment to patient safety. I recognise that there are severe pressures on the health service, but as long as safety is at the heart of everything, we will reduce avoidable harm to patients.

My ambition is a health and social care system that listens, hears and acts with speed and compassion to the voices of patients.

> ‘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. In essence, everything we do as a healthcare system because everything we do is about patients.
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> I want us to be able to look back in astonishment on the way that we operate now. 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.’
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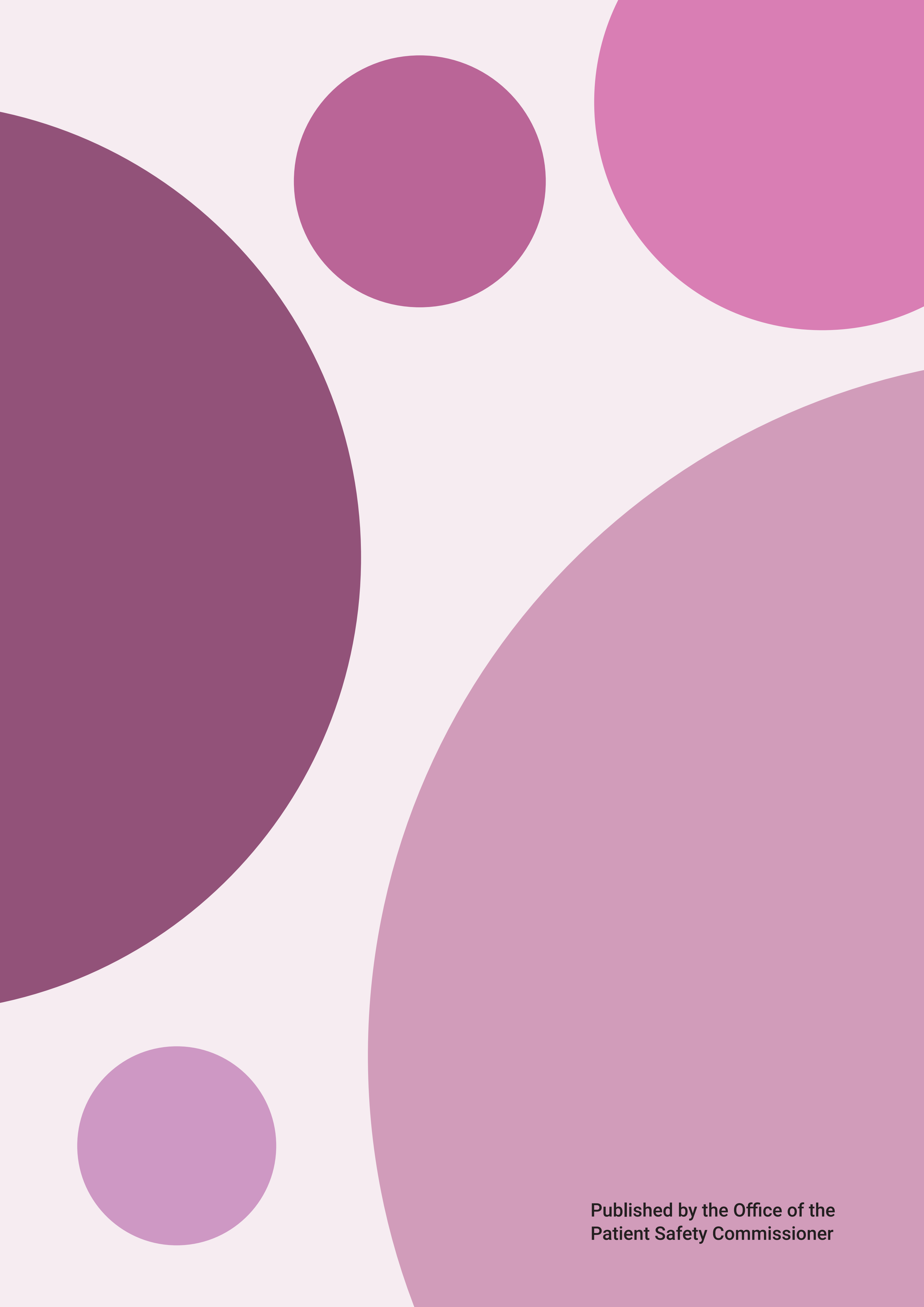

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