Patient Safety Commissioner

Annual Report 2022-23

July 2023

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Introduction

My role as Patient Safety Commissioner was set up because the Independent Medicines and Medical Devices Safety review (IMMDS) demonstrated that patients' voices were not heard in relation to medicines and medical devices, including sodium valproate, pelvic mesh, and hormone pregnancy tests.

In the first seven months, I have been listening hard to the voices of patients and their representatives. What I have learnt is that over two years from when the IMMDS was published, this problem extends well beyond the issues identified by the review. The safety concerns that patients raise are often an early warning of future adverse events and listening and acting on these lead indicators reduces the risk of harm occurring. I am here to speak for patients, to amplify their voices, and to inspire and lead change.

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 have 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 the DHSC nor NHS England have a patient representative on their Boards or hear a patient story. 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 avoidable deaths.

Many positive steps have already been taken, including the national patient safety strategy, the new methodology for investigating incidents and the appointment of Patient Safety Partners to bring the voice of the patient to the boards of NHS organisations. There are pockets of excellent practice from which we must learn. Hormone pregnancy tests were withdrawn from the market decades ago. Pelvic mesh has been paused and a national specification for mesh removal centres drawn up. Sodium valproate can only be prescribed with a pregnancy prevention programme in place. I am pleased that sodium valproate dispensing to women of childbearing potential was reviewed in the national community pharmacy audit this year and I await the results.

But I have heard from patients and their families that the concerns described in the IMMDS 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. On my second day in post, I was alerted to a range of worrying and potentially dangerous issues. A patient sent me a photo of sodium valproate dispensed in a plain white box with no warning labels. I raised this to the Chief Executive of the General Pharmaceutical Council and am pleased that immediate actions have followed. A letter was sent the next day to 91,000 pharmacists and I have followed this up with superintendent pharmacists. I have discovered, through my own clinical practice as a GP, that the electronic GP prescribing system does not align prescription size to packaging size, so boxes need to be split under current legislation.

Patients taking sodium valproate are not routinely having an annual review by a specialist prescriber and not all have signed an annual risk acknowledgement form. The provision of highly effective contraception is also patchy - in the last audit only 64% of women were using highly effective contraception - so 36% of women taking sodium valproate risked conceiving on a teratogenic medicine, known by doctors to cause harm to an unborn child. This is not because of inaction, it is because health leaders don't understand the health system including the funding arrangements, don’t own the problem, and don’t always work effectively together, leaving patients to pick up the pieces.

Meanwhile, by listening to patients harmed by pelvic mesh, I had no confidence that the national specification for specialist mesh centres was developed with involvement of the very patients who have been harmed. The language blamed patients and did not make it clear that patients can attend the mesh removal centre of their choice, so women may face the same surgeon for mesh removal who inserted it. I am pleased that NHS England has taken this feedback on board and made the necessary changes. However, patients suffering pain and disability are still not being heard, not being referred to specialist pelvic mesh centres, and experience patchy provision of services. The waits for appointments are long, travel is expensive and time consuming, and the centres do not all have the holistic wraparound care recommended in the IMMDS review. The very centres set up to listen and act on patients’ concerns do not all have patient forums established.

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.

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 fluoroquinolones, topical steroid treatment, antidepressants, prescribed benzodiazepines, and painkillers. From people with concerns about the Yellow Card reporting system, the Covid-19 vaccine damage payment scheme, the timing of medicines administration, supply chain issues around syringe drivers, PIP breast implants, and the regulation of electroconvulsive 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 benefits to patient safety.

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. I have met with patients, campaigners and representatives including parliamentarians who have helped to amplify patients’ voices. I have found that when people voice inconvenient truths, the system turns its back and fails to listen and act. Patients tell me they feel that efforts to listen and engage are tokenistic and a tick box exercise. Reviews have been delayed due to political upheaval. Meanwhile, patients are still suffering.

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 medical devices and amplify your voice, 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.

In the first financial year from a standing start, I have recruited a team of four people and we have established the governance of the Office, including ways of working, MOUs, a provisional framework agreement, established my priorities and a work programme, set out the business model required to achieve the objectives of the role, been represented at local, regional, national and international events, responded to correspondence from over 150 people, set up an Advisory Group and held the first meeting, co-founded a network of Patient Safety Leaders and a network of organisations that listen to patient voices, engaged widely with many patients, patient groups and charities, with the health sector and beyond, set up social media and procured and designed a website, visited health providers, met with Parliamentarians, attended conferences, round tables, and conducted press interviews, radio and television appearances.

I and my team have met with many members of the patient safety family, including patient safety specialists, managers and partners, medicine device safety officers and medicine safety officers and senior leaders, and worked with all the professional regulators to improve the alignment of patient consent.

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.

In my hundred days report I set out the immediate steps that need to be taken to ensure that patients' voices are at the top of the agenda. I want us to be able to look back in astonishment on the way that we operate now. Without listening and acting on patient voices, safety continues to be compromised and patients and families continue to suffer the consequences of harm. I want to see patient voices included from the start of every project, co-designing and co-producing so that the needs of all patients and families are met. So that people get the information and data they need to make the right choices about their healthcare involving medicines and medical devices, have the psychological safety to voice concerns knowing the right action will be taken and that the system truly responds swiftly, compassionately and in a joined-up way. This is the moment to set a new course with shared decision-making and patient partnership as our destination.

I would like to thank everyone who has helped in these endeavours, including the Patients Association, Baroness Julia Cumberlege, and the sponsor team at DHSC. I would also like to take the opportunity to pay tribute to my team who continue to demonstrate exceptional patient-centred values and incredible hard work.

Henrietta Hughes, Patient Safety Commissioner

Context

The Independent Medicines and Medical Devices Safety review set out the devastating impact on people’s lives when patients’ voices go unheard. To keep patients safe, it is vital that they receive the information to make the right decision about their care, that their voices are heard and acted on, and that the health system responds in a swift, co-ordinated, and compassionate way.

Recommendation 2 from the review was the appointment of an independent Patient Safety Commissioner to promote the safety of medicines and medical devices and to amplify the voices and views of patients and the public so that future harm is avoided.

The Patient Safety Commissioner (PSC) was appointed on 13 July 2022 and took up her post officially on 12 September 2022. To year end 2022-23, over 150 correspondents have raised a wide range of different, important safety matters and immediate actions have been taken as a result to keep patients and their families safe. It is evident, however, that the Office of the Patient Safety Commissioner is not currently resourced sufficiently to provide support, guidance, or advice on the broad range of issues raised by this correspondence.

On her appointment, the PSC set out her plans in the role. This table lists them and progress:

Ambition	Action
To listen to patients, focusing on those groups who face the greater barriers	Undertook an extensive engagement programme, meeting with patients in trusts and with patient representative groups
To explore methods to make processes safe for patients by tracking the pathway of medicines and medical devices from research and development to manufacture, publication, testing, approval, licensing, sales, implementation, use, prescribing, dispensing and follow up	Engaged with MHRA, CHM, ABPI, ABHI, pharmaceutical companies, NHS England, the GPhC, superintendent pharmacists, government officials, GPs and secondary care doctors, and new electronic systems
To convene a network of the many bodies responsible for the safety of medicines and medical devices	Worked to develop the Patient Safety Leaders Informal Network and assumed the chairmanship along with the national patient safety director
To identify best practice and establish ways of working so that patient safety and patient voice are at the heart of healthcare design and delivery	Developed new networks to access the frontline and collate and share best practice on the PSC website

To review how people can easily find the information that they need to make informed decisions about medicines and medical devices	Influenced key stakeholders in the NHS, the independent healthcare sector, the MHRA, pharmaceutical companies, trade bodies, and manufacturers to make information patient-centred
To improve ways that patients, service users and their families can meaningfully give timely feedback, and how this leads to change	Worked with patient groups, Patient Safety Partners, Patient Safety Specialists, the CQC and Care Opinion to identify and promote good practice
To explore how people in the health system, from individual clinicians to national bodies, can improve their listening skills, and feel safe and empowered to act	Worked with healthcare providers, regulators, staff representative groups and Patient Safety Partners to understand the barriers to listening and acting

Activity

The PSC has spent the first seven months in the role listening to patients and highlighting their concerns to the health system and to government. Following these discussions, she agreed her three priorities: pelvic mesh, sodium valproate, and culture change. The first two are priorities because these interventions are still resulting in ongoing harm to patients and their families and the third - culture change in the health system - is essential before long-term improvements to patient safety can be made. She has built networks and alliances across the system, bringing together disparate organisations to influence improvements to patient safety.

The PSC has achieved many specific successes during this period: she influenced the dispensing of sodium valproate in original packaging with warnings about the risks to the foetus. Her work influenced the decision by NHS England and the Pharmaceutical Services Negotiating Committee to focus on sodium valproate prescribing in their 2023 community pharmacy audit. She encouraged regulators to streamline information about highly effective contraception as part of the pregnancy prevention programme for patients taking sodium valproate in an attempt to reduce the number of babies born exposed to the medication. More broadly, the PSC challenged NHS England to begin including patient voices in the design and language of specialised services national specifications and met with its chair to encourage the hearing of patient stories at its main board.

The PSC's first 100 Days Report, summarising her plans for the future year, was launched at a major event at Central Hall, Westminster, in February with leading patient safety experts, patients with lived experience, and government officials. The report’s key finding - that unless the health system's culture changes, it is heading straight back to the Mid-Staffs scandal - was widely highlighted across the media, The PSC has contributed to a range of inquiries and reports, including:

- the MHRA-commissioned Whitehead review of equity in medical devices
- the Infected Blood Inquiry
- the Hewitt review of the oversight, governance, and accountability of integrated care systems.

She provided evidence to the Scottish Government’s Health, Social Care and Sport Committee on the Patient Safety Commissioner for Scotland Bill, which will see a new patient safety commissioner for the country.

Her office developed Memoranda of Understanding (MoUs) with the Professional Standards Authority (PSA) and the General Pharmaceutical Council (GPhC) and began work on similar agreements with other relevant organisations. She set up an Advisory Group to advise and support her in the new role and held the first meeting.

A team has been recruited and the governance structure for the office developed. A location has been identified in the NHS Confederation’s office in Westminster, central London, with plans to move in shortly.

Engagement

The PSC has undertaken an extensive engagement programme using meetings with patient groups, visits to hospitals, clinics, and innovative new services, as well as speaking opportunities, to listen to patients and professionals on how to improve patient safety in relation to medicines and medical devices. The primary focus of this programme was to provide her with the opportunity of listening directly to patients, including those who are less often heard, to understand their experience of the health system in relation to medicines and medical devices. She has found that the issues raised by the IMMDS are still live and that patients’ views are still dismissed or ignored, leaving patient safety at further risk.

The engagement programme has included meeting:

- Patient Safety Partners, who are providing challenge and insights to NHS trusts
- patient safety specialists and managers

- medication safety officers and medical device safety officers
- regulators
- think tanks
- manufacturers
- pharmaceutical companies
- healthcare leaders in trusts and ICSs
- royal colleges
- educators
- lawyers
- charities, including the Epilepsy Society and Parkinson's UK

and developing a network of influence to place patient safety at the heart of the health ecosystem. She has also met with NHS England CEO Amanda Pritchard and the National Data Guardian. She has regular meetings with patient representative groups, which are supporting those who have been harmed by medicines and medical devices, to update them on her work.

Presentations:

The PSC has presented to major 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 Medical Device Safety Officer and Medical Safety Officers conference
- the RCGP mental illness and suicide roundtable
- the Sodium Valproate roundtable
- the Healthcare Safety Investigation Branch (HSIB) Patient and Family roundtable and

- the Infection Management Coalition meeting

In December she addressed the 11 Downing Street seminar, 'National State of Patient Safety: what we know about avoidable harm in England', providing a hard-hitting assessment of the flaws in the current system and the need for urgent improvement. The PSC also took part in the Patients Association patient participation week and addressed the Health and Social Care Regulators Forum and the GS1 UK Healthcare Advisory Board. She was invited to address the World Patient Safety Movement Summit in California and her Office was represented at the 5th Global Ministerial Summit on Patient Safety in Switzerland.

Visits:

She has visited services across the country to learn about how they are improving patient safety, including:

- the specialist mesh centre at University College London NHS Foundation Trust
- University Hospital Southampton NHS Foundation Trust
- Leeds Teaching Hospitals NHS Trust
- Maidstone and Tunbridge Wells NHS Trust
- Kingston Hospital NHS Foundation Trust
- Mid and South Essex ICS

and viewed innovation in action, including Scan4Safety, a barcode system currently being piloted in the NHS, PEP Health, a platform that analyses millions of pieces of patient feedback to provide details on reasons for improving or declining patient satisfaction, Care Opinion, a feedback platform for patients to share their stories, and Written Medicine, a web-based software programme that provides bilingual medicine package labelling and discharge summaries in eleven languages.

Parliamentary liaison:

A central part of the PSC role is to raise the voice of patients with government and to explain the issues they face. To this end, she has met with MPs and members of the House of Lords who are interested in the safety of medicines and medical devices to discuss what she has heard directly from patients.

The PSC has met with Steve Brine, chair of the Commons Health and Social Care Committee, and addressed its review of progress on the IMMDS review. She also addressed members of the First Do No Harm All-Party Parliamentary group just before the launch of her First 100 Days Report in February. She met with Feryal Clark, the Shadow Minister for Primary Care and Patient Safety, and MPs representing patient groups with concerns about harms from medicines and medical devices.

Connecting organisations:

A key element of the PSC's role is to bring individuals and organisations together to provide a co-ordinated approach to patient safety in England:

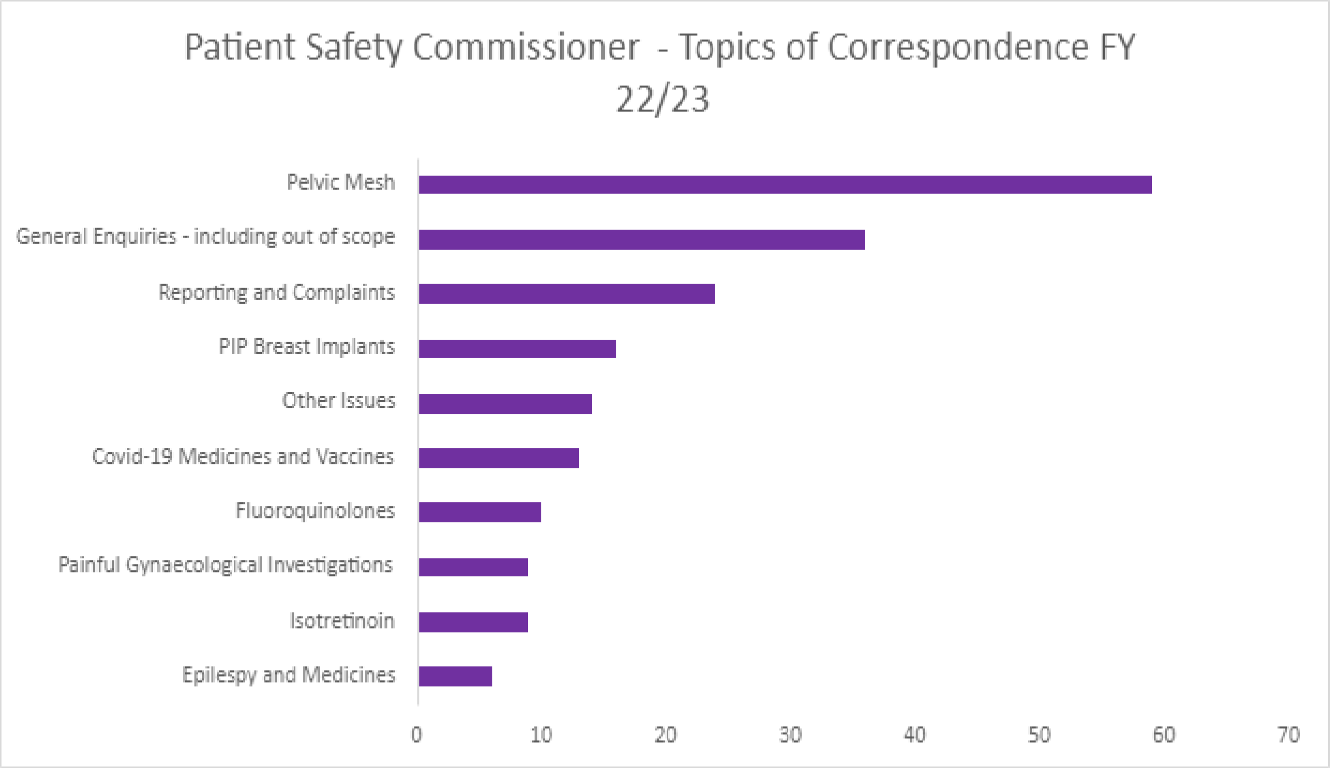
- The PSC co-founded the Patient Safety Leaders Informal Network and now co-chairs it alongside the National Director of Patient Safety
- She co-founded the Patient Voice network
- She worked closely with the CQC Improvement Programme, NHS England’s Pharmacy Advisory Group as well as the Medicine Safety Improvement Programme (MedSIP) Board

The PSC also:

- worked with research institutes, pharmaceutical companies, and manufacturers to identify barriers to patient safety and to promote and disseminate good practice
- began reviewing how people find the information they need to make decisions about medicines and medical devices and how patients provide timely feedback
- explored how the health system can improve listening skills

Correspondence

The chart below shows the correspondence the PSC received up until April 2023 by topic:



Communications

One of the PSC’s initial aims was to inform patients, the public and the health system about her role. This was achieved using press, social media, TV appearances, podcasts, and keynote speeches to explain her aims.

This work has included:

- highlighting the risks of taking sodium valproate in pregnancy on the BBC1 series 'Con or Cure'
- contributing to the Doctors in Distress seminar on the mental health burden on healthcare workers
- creating a podcast for the Medical Women’s Federation
- presenting to a seminar run by the Guild of Health Writers

Media played a key role in informing the public of the new role. This included:

- providing insight and comment to stories across national and trade media, including interviews with The Independent, the i newspaper, and the Sunday Times
- appearing on BBC Radio 4's Women's Hour
- being quoted regularly in the Sunday Times's ongoing campaign on sodium valproate
- writing opinion pieces for the Health Service Journal
- commenting on a range of stories in The Pharmaceutical Journal

Her office set up a Twitter account which soon had over 1,000 followers, and this number continues to grow. It also began planning for a new Patient Safety Commissioner website, which will engage patients, professionals, and the public about the work of the Commissioner.

The PSC has also written a series of blogs for publication across health media covering a wide range of topics, including how healthcare leaders can connect with patients, how the system needs to listen to a diverse range of patients, and how health leaders need to shift their focus from efficiency and finance to safety.

Finance

The Commissioner's Office retains the use of the Department for Health and Social Care's banking facilities to run our day-to-day operations. This arrangement is consistent with the provisional Framework Agreement, to be published as soon as finalised, which sets out that while the Commissioner'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 Commissioner's annual expenditure is included within the Department's Annual Report and Accounts.

Business Plan for FY 23/24

As part of establishing the first ever Office of the Patient Safety Commissioner (OPSC) there are a number of set-up tasks. These include setting out an understanding of the remit and whether it is fit for purpose, whether the Office is sufficiently resourced to achieve its objectives and how patient voice can be most effectively amplified across the system. The Business Plan for FY 23/24 which is set out below was submitted to the Department in January 2023. At the time of writing this report the Commissioner remains in discussions with the Department about effective levels of resourcing and budgetary allocations. This position is correct as of 4 July 2023.

While the FY 22/23 can broadly be considered a set-up phase, it is necessary to see some set-up elements as key parts of FY 23/24. This FY will focus on the achievement of the PSC’s 12-month priorities, which will be set out in a publication in summer 2023. It is expected that this year will be characterised by the successful completion of the public consultation on principles, which, alongside the establishment of the Advisory Group, is a statutory requirement. This work will be subject to sufficient resourcing levels. To help the government and the health system to listen to patients and to prevent future harm, the PSC will also begin the work of establishing recommendations for the healthcare system on a range of issues, including those raised by patients since the operationalisation of the OPSC.

Resource Expansion:

The PSC has been clear with the Minister for Mental Health and Women’s Health Strategy and the DHSC that current resourcing levels are insufficient to achieve the Department’s and the PSC’s objectives. This business plan sets out the need for resource expansion to a total team size of 16. The OPSC requires:

- Policy and Strategy Unit - the OPSC will require a policy lead each of the three core workstreams: pelvic mesh, sodium valproate, culture change. In addition, each workstream will require more junior support

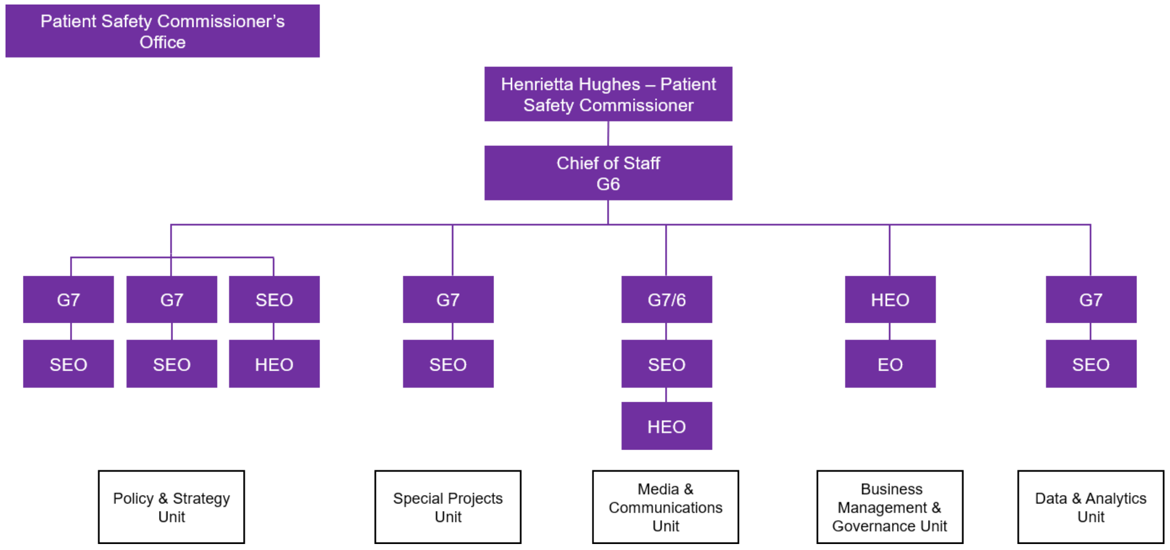
- Special Projects Unit - the OPSC will require a special projects team to look at the issues which are brought to the PSC's attention on an ad hoc basis. This includes from patient correspondence or stakeholder engagement across the sector

- Media and Communications Unit - the OPSC will require a Media and Communications lead with additional support provided by two more junior members of staff. This Unit will focus on patient and public engagement activities alongside media and presentations

- Business Management and Governance Unit - the OPSC will require this Unit to oversee the correspondence process, milestone tracking, risk management and diary oversight

- Data and Analytics Unit - the OSPC will require a data branch which can provide the necessary novel research, analytics, and research projects to advance the OPSC objectives

These teams will be led by the Patient Safety Commissioner, with oversight provided by the Chief of Staff. The Chief of Staff will deputise for the PSC where necessary, lead discrete projects, and provide the strategic direction for the office. An organisation chart is shown below.



As well as the consultation on the Better Patient Safety principles referred to in the Business Plan, the PSC will issue a resource for patients who are suffering from side effects of pelvic mesh to bring to their GPs to obtain appropriate referral and treatment.

The PSC will also start a major project on a redress scheme for the patients and their families who have been harmed by sodium valproate and pelvic mesh as requested by the Minister for Mental Health and Women's Health Strategy.