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Health and Social Care
Committee

Follow-up on the IMMDS report and the Government's response

Sixth Report of Session 2022–23

*Report, together with formal minutes relating
to the report*

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Health and Social Care Committee

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Follow up the IMMDS report and the Government's response

1. On 13 December 2022 we held an evidence session on the Independent Medicines and Medical Devices Safety (IMMDS) review's report titled 'First Do No Harm'. The report was published in July 2020. The review was asked to examine how "the healthcare system in England responds to reports about harmful side effects from medicines and medical devices and to consider how to respond to them more quickly and effectively in the future", specifically in regard to three medical interventions: vaginal surgical mesh, sodium valproate and Hormone Pregnancy Tests.¹ The purpose of our evidence session was to hear from those affected by the medicines and medical devices reviewed, from the review team and from the Minister and Government officials on what progress had been made on the report's recommendations.

2. We would like to thank all the witnesses, but particularly the three witnesses who spoke from the perspective of their lived experience, Kath Sansom, Emma Murphy and Janet Williams. They provided us with powerful and moving evidence of their experience and we are grateful to them, and to their families, who continue to fight for those affected by these medical interventions. We had hoped to hear from Marie Lyon on behalf of the Association of Children Harmed by Hormone Pregnancy Tests, however due to ongoing litigation, we were unable to do so at this time.² When legal proceedings allow, we shall return to look at the issue of Primodos, within the wider context of the IMMDS review.

3. The two medical interventions which we focused on were surgical mesh and sodium valproate. During our session, we heard heart-breaking accounts of how the health system had failed to provide proper guidance, care and support, even when it was known that harm was occurring. Although the Government made a full public apology to those affected after being recommended to do so in the IMMDS review report, we are concerned about the speed at which the Government is progressing against its commitments. In this report we make some recommendations which we hope will encourage the Government to proceed more swiftly on recommendations made more than two years ago. The recommendations in the IMMDS review report serve to address years, and sometimes decades, of hurt, and it is important that the Government makes significant progress soon.

Surgical mesh

4. Surgically inserted vaginal mesh implants are used in some surgical procedures to provide additional support when repairing weakened or damaged tissue. However, in recent years concern has been raised around complications which can occur with the use of this mesh in urogynaecology procedures to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). Complications include persistent pain, sexual problems, mesh exposure through vaginal tissues and occasionally injury to nearby organs such as the bladder or bowel. This has been acknowledged by NHS England, NICE and others, but there is limited evidence collection of the long-term adverse effects following these

1 IMMDS Review, [First Do No Harm – The report of the Independent Medicines and Medical Devices Safety Review](#), (July 2020)

2 Standing Orders of the House of Commons, Appendix: [Orders and Resolutions, Matters sub judice, Resolution of 15 November 2001](#)

procedures.³ In July 2018 the IMMDS review report recommended an immediate stop to using vaginally inserted surgical mesh for stress urinary incontinence procedures. The Government accepted this recommendation and put a pause on all procedures where mesh is inserted vaginally.⁴ Kath Sansom from Sling the Mesh campaign said that she had not been told there were any risks associated with inserting surgical mesh or that it was made of plastic, and that she had assumed she could easily remove it if she wanted to. Going in for her procedure in June 2015, Kath had no worries about this surgery. However, after her surgery, her life changed:

I went in super fit. I used to high-board dive—yes really—off the top boards. I used to box and mountain bike. I was super fit, and that was half the reason why I suffered from stress incontinence. I was so active. I went in super fit and came out in enormous amounts of pain. At first, I just assumed it was the surgery, but as the days went on the pain got worse in my back, hips and groin. It was like a scraping and scratching pain internally. It felt like I had been battered with a baseball bat down my legs. It was horrific.⁵

5. It is difficult to know exactly how many women have been affected by adverse effects following mesh insertion prior to the procedure being paused, or the extent of their harm.⁶ It is vital to understand the scale of this issue, as there are no central lists that could be used to follow up with patients who have been through this procedure, in order to ensure that the system in place to treat women who have experienced harm is appropriate. It is unacceptable that women still suffer from having this device implanted, some after not being told about the possible risks. We will continue to press the Department on this, as harm and complications from this device are likely to arise for years to come, and it is essential that women affected have access to timely and proper care. As Kath Sansom told us during the session, not everyone who has had mesh implanted has experienced adverse effects yet, but there is a risk that they might in the future:

The key thing with mesh is that it is a bit of a ticking time bomb. In many ways I feel lucky that my complications were instant, because it was very clear to see that they were caused by mesh surgery. We have some women coming to the page and they might be fine for two years, five years or eight years. We even have someone 15 years after her mesh sling for incontinence was implanted.⁷

6. We were encouraged to have confirmation from Dame June Raine, Chief Executive of the Medicines and Healthcare products Regulatory Agency (MHRA), that surgical mesh will be put into the highest risk class (class III) for medical devices,⁸ and look forward to an update from the Department on this.

7. During our evidence session Kath Sansom told us that she wished in hindsight, that she could have been prescribed physiotherapy rather than mesh surgery. We asked Celia

3 The Independent Medicines and Medical Devices Safety Review, Briefing Paper [CBP 9274](#), House of Commons Library, February 2022

4 The Independent Medicines and Medical Devices Safety Review, Briefing Paper [CBP 9274](#), House of Commons Library, February 2022

5 Oral Evidence taken on 13 December 2022, [HC \(2022–23\) 689, Q10 \[Kath Sansom\]](#)

6 IMMDS Review, [First Do No Harm – The report of the Independent Medicines and Medical Devices Safety Review](#) (July 2020), p. 5

7 Oral Evidence taken on 13 December 2022, [HC \(2022–23\) 689, Q17 \[Kath Sansom\]](#)

8 Oral Evidence taken on 13 December 2022, [HC \(2022–23\) 689, Q71 \[Dame June Raine\]](#)

Ingham-Clark (Medical Director for Professional Leadership and Medical Workforce, NHS England) about why treatment through physiotherapy, rather than surgical mesh implants, had not been championed more to treat conditions such as stress incontinence. Ms Ingham-Clark told us that physiotherapy as an option is “quite important” and told us that this was one of the particular strengths of the new specialist mesh centres:

Every woman who is referred there is discussed by a team that includes a physiotherapist, a nurse specialist, a psychologist, a pain management specialist and so on, so the opportunities to give women good choices that are effective for them are there. I regret that they were not always there in the past.⁹

8. We look forward to seeing data on how many women are referred, and their satisfaction rates with the care that they receive there, in due course.

Sodium valproate

9. Sodium valproate is a medicine used to treat epilepsy and bipolar disorder. It's occasionally used to prevent migraine headaches. If taken during pregnancy, sodium valproate can cause problems for a baby's development, including birth defects and long-term learning difficulties.¹⁰ The collective name for the defects, disorders and developmental issues some children experience after being exposed to sodium valproate in-utero is Foetal Valproate Spectrum Disorder (FVSD).¹¹ The MHRA's guidance states that the product information for this medicine has included a warning about the possible risk of birth defects since 1974. The guidance also states that the MHRA has worked with healthcare professionals and patient groups to ensure that female patients are better informed about the risks.¹² According to Government guidance, sodium valproate must not be used in any woman or girl able to have children unless there is a pregnancy prevention programme (PPP) in place.¹³ Emma Murphy from In-FACT told us:

I was diagnosed with epilepsy aged 12. I was started on sodium valproate and pretty much just left on it, to be honest. When it came to starting a family, my husband and I questioned at every appointment whether valproate would harm during pregnancy. We were never warned at all. I was always told that it is the safest medicine to take during pregnancy to control the seizures. I now obviously have five children affected, and they are all diagnosed with foetal valproate spectrum disorder, along with autism.¹⁴

10. Since April 2018, 286 women have been prescribed sodium valproate in a month in which they were pregnant. We are worried about the fact that 17 of them were identified as new additions in the most recent 6 months (data from October 2021 to March 2022),¹⁵ as some of those 17 women are likely to give birth to children harmed by the teratogenic

9 Oral Evidence taken on 13 December 2022, [HC \(2022–23\) 689, Q67 \[Celia Ingham-Clark\]](#)

10 NHS, [Sodium Valproate](#), accessed 3 January 2023

11 IMMDS Review, [First Do No Harm – The report of the Independent Medicines and Medical Devices Safety Review](#) (July 2020), p. 98

12 MHRA, [Valproate use by women and girls](#), accessed 3 January 2023

13 DHSC, [Valproate use by women and girls](#), accessed 3 January 2023

14 Oral Evidence taken on 13 December 2022, [HC \(2022–23\) 689, Q1 \[Emma Murphy\]](#)

15 NHS digital, [Medicines and Pregnancy Registry - Antiepileptic use in females aged 0 to 54 in England: April 2018 to March 2022](#), 29 September 2022

effects of this medication.¹⁶ It is unacceptable that children are still being born to mothers who were not properly advised and supported to change their medication to one less likely to harm their unborn child. There have been important improvements made, but we are concerned that unless the Government ensures there is a rigorous system in place, standards might slip.

11. The 2019/20 Community Pharmacy Quality Scheme Valproate Audit Report, published in August 2022, worryingly showed that the MHRA safety requirements for the use of sodium valproate in women and girls of childbearing age are not being fully met. Amongst other things, the report showed that 17.6% of patients reported that within the last 12 months they had not discussed the need for appropriate contraception while on sodium valproate with their GP or a specialist and 9.1% were unsure if they had had such a discussion.¹⁷ During our session we also heard that many women of childbearing age on sodium valproate had poor experiences of the PPP, meant to be in place to minimise risk of a woman on sodium valproate becoming pregnant. Janet Williams from In-FACT told us:

The pregnancy prevention programme really has not got going. It has been there since 2018, and there are still women coming to us saying that they have not been called in, or that they have had an appointment but the doctor has not brought up the topic. There are ladies out there who do not have an epilepsy review or a bipolar review, so the information is not getting through.¹⁸

12. On 7 December 2022, Rt Hon Caroline Nokes MP led an adjournment debate titled Fatalities relating to foetal valproate spectrum disorder (FVSD), which detailed the case of Jake Aldcroft who at 21 years old sadly passed away after an infection triggered by problems with his kidneys. Jake was the first person to ever have had FVSD listed as a contributing factor of death on the coroner's report. Jake's mother says that when she ingested sodium valproate whilst pregnant, she was never advised that this may cause harm to her unborn child.¹⁹

13. Although the number of women on sodium valproate whilst pregnant is thankfully decreasing year on year, the effect this drug has had and continues to have on thousands of children (some now adults) is devastating. Our thoughts remain with the families affected, who are continuing to battle the harmful effects. We will return to the important issue of redress and support later in this report.

Data collection

14. In a letter to us, Emma Murphy and Janet Williams from In-FACT state that some of the families affected by FVSD report seeing second-generation problems, with some of those exposed before they were born seeing their own children affected by similar issues.²⁰

16 Valproate and Fetal Anti-Convulsant Syndrome, Debate Pack [CDP 2017/0186](#), House of Commons Library, October 2017

17 NHS England, [Community Pharmacy Quality Scheme 2019/20 Valproate Audit Report](#), 11 August 2022

18 Oral Evidence taken on 13 December 2022, [HC \(2022–23\) 689, Q15 \[Janet Williams\]](#)

19 HC Deb, 7 December 2022, [col 471](#) [Commons Chamber]

20 [Letter from In-FACT to the Chair](#), 20 December 2022

15. In a letter sent to us following the session, Dame June Raine stated that there is data suggesting that people affected by sodium valproate exposure as an unborn baby could potentially pass on effects to their children. Dame June also pointed to European-commissioned studies into transgenerational effects of sodium valproate which following a delay due to Covid-19, is expected to publish results by the end of 2023.²¹ We are encouraged to hear about this research being forthcoming, but we are concerned that data on reports of transgenerational effects has not been collected in the UK. We cannot understand how it is not in the interest of the Government to monitor transgenerational effects in those affected here in the UK, and would welcome an explanation from the Minister on this.

16. This lack of data collection and long-term effects monitoring is something we are especially concerned about, given recommendation 6 (a revision of MHRA regulation of adverse reporting of medicines and medical devices) and recommendation 7 (a central patient-identifiable database collecting key details of the implantation of all devices at the time of the operation) of the IMMDS report have not been acted on. The IMMDS review team were clear that the aim of these two recommendations was to ensure that patient experience and outcome were collected and registered.²² In a letter to us, the IMMDS review team commented on the lack of available data:

This absence of data means the system did not—and still does not - track patient outcomes measured with direct patient input (PROMs and PREMs) or detect trends of concern. That represents a serious risk to patient safety. The best way to assess the quality and safety of a treatment is to measure the outcome.²³

17. The IMMDS review team stated in their letter that the importance of keeping a register with patients' data was something which NHS England (NHSE) itself recognised in the case of surgical mesh.²⁴ NICE recommended such a database or register should be kept when mesh started to be used for SUI and pelvic organ prolapse in 2003.²⁵ In their letter, the review team estimated that 100,000 women were treated with surgical mesh, and that as many 10% had severe long-term problems.²⁶ In 2018 NHS Digital published retrospective data relating to patients who have had a urogynaecological procedure for the treatment of urogynaecological prolapse or stress urinary incontinence, including those where mesh, tape or their equivalents have been used, between 2008 and 2017. NHS Digital state that the data is “classified as experimental” and should therefore be used with caution.²⁷ The NHS Digital data does not include any mention of monitoring patient outcome or experience. Kath Samson told us:

[...] there is no mandatory logging of adverse events of anything by doctors. That is not just mesh—it is anything, be it medication, a medical device or

21 [Letter from Dame June Raine to the Chair, 17 January 2022](#)

22 IMMDS Review, [First Do No Harm – The report of the Independent Medicines and Medical Devices Safety Review](#) (July 2020), p. 47

23 [Letter from IMMDS review team to the Chair, 20 December 2022](#)

24 [Letter from IMMDS review team to the Chair, 20 December 2022](#)

25 IMMDS Review, [First Do No Harm – The report of the Independent Medicines and Medical Devices Safety Review](#) (July 2020), p. 163

26 [Letter from IMMDS review team to the Chair, 20 December 2022](#)

27 NHS Digital, [Retrospective Review of Surgery for Urogynaecological Prolapse and Stress Urinary Incontinence using Tape or Mesh: Hospital Episode Statistics \(HES\), Experimental Statistics, April 2008 - March 2017, 17 April 2018](#)

a vaccine. It is not mandatory for a healthcare professional to log it. We know from checking data that two thirds of mesh complications were not logged for that reason. The MHRA was able to keep saying that mesh was a low-risk, satisfactory treatment option simply because the adverse events were not logged.²⁸

18. In their letter, the IMMDS review team criticised the current use of the National Joint Registry model which has only resulted in 15% compliance, despite the then Secretary of State accepting recommendation 7 of the review and at the time committing to 100% compliance. The IMMDS review team pointed to the Hospital Episode Statistics (HES Data) and the OPCS classification of interventions and procedures, which records all operations carried out in the NHS (and “increasingly” in the private sector). According to the IMMDS review team there is “a move” to record this data at the time of surgery, so that it can be validated by the operator and, with patient consent, used for follow-up purposes, which they conclude is a positive change and should be implemented widely.²⁹

19. The IMMDS review report recommended a retrospective audit of women who had pelvic mesh surgery, which according to the IMMDS report has been discussed with NHS Digital. The IMMDS report stated such an audit would likely “constitute a representative sample providing far greater detail on mesh complications in the decade after surgery”. In response to a written question asked by Feryal Clark MP on whether this audit would take place, the Minister Maria Caulfield MP stated:

We accepted the Independent Medicines and Medical Devices Safety Review’s recommendation to undertake a selective retrospective audit of a defined cohort of women who have undergone mesh procedures. NHS Digital has undertaken an audit of all pelvic floor surgery completed in 2010 to generate a historical baseline of outcomes by procedure type and to support further research and analysis. This audit was conducted using Hospital Episode Statistics data and other data using the identified National Health Service cohort of patients and the longitudinal record to observe outcomes where possible. The audit has been completed and is undergoing peer review prior to publication in 2023.³⁰

20. The “other data using the identified NHS cohort of patients” referred to in the Minister’s written response was not used in this audit. On 6 January 2023, the Minister provided a response to a written question asked by Emma Hardy MP, in which the Minister stated:

In our previous response to Question 103061, we stated that the audit was conducted using Hospital Episode Statistics data and other data using the identified National Health Service cohort of patients. However, NHS Digital has confirmed that only Hospital Episode Statistic data was used in the audit and no other data was employed. Patients were not contacted as part of this audit. We are arranging for the record to be corrected.³¹

21. However, as outlined during our evidence session by Kath Sansom, the issue with using HES data is that some complaints of mesh-related complications may never make

28 Oral Evidence taken on 13 December 2022, [HC \(2022–23\) 689, Q18 \[Kath Sansom\]](#)

29 [Letter from IMMDS review team to the Chair](#), 20 December 2022

30 HC Deb, 13 December 2022, [UIN 103061](#) [Commons written answer]

31 HC Deb, 13 December 2022, [UIN 110813](#) [Commons written answer]

it into the data collection in the first place, unless the woman is correctly identified as suffering adverse effects from surgical mesh and then referred on from primary care.³² In a letter we received following the session, the Sling the Mesh campaign similarly criticises this audit for using HES data because this data fails to adequately capture complications.³³

22. Without records of which patient has undergone which procedure, or been prescribed which drug, the health system will continue to, in the words of the IMMDS review team, “fly blind”. We recommend that the Government urgently ensures that the accepted recommendations 6 and 7 of the IMMDS review are fully implemented.

23. Although the retrospective audit of mesh implants is an encouraging first step, it will be unlikely to reflect and take into account all of the adverse effects women have experienced due to the nature of data used in the audit. We therefore recommend that the Government consider an alternative strategy for how to pro-actively contact those who have had the procedure about their post-operative experiences and possible side effects.

Register of interests of healthcare professionals and payments by companies

24. The IMMDS review recommended that the General Medical Council's (GMC) register for clinicians should include a list of financial and non-pecuniary interests for all doctors (including clinical interests, recognised and accredited specialisms). It also recommended that there should be mandatory reporting for the pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions and individual clinicians.³⁴ The Government accepted this recommendation “in principle”, but stated that:

We agree that lists of doctors' interests should be publicly available, but we do not think that the GMC register is the best place to hold this information. Our approach is to ensure it is a regulatory requirement that all registered healthcare professionals declare their relevant interests, and that this information is published locally at employer level.³⁵

25. During our evidence session William Vineall, Director of NHS Quality, Safety and Investigations at the Department of Health and Social Care, told us that the timing and location of local pilots to implement this recommendation were due to be announced, but that he expected that the pilots would “run during 2023 and then to bring forward results after that”.³⁶ However, in a subsequent letter, the Minister Maria Caulfield MP stated that full implementation of the recommendation will begin in 2023.³⁷ We therefore assume that the pilots may be concluded, and implementation may be proceeded with, in

32 Oral Evidence taken on 13 December 2022, [HC \(2022–23\) 689, Q18 \[Kath Sansom\]](#)

33 [Letter from the Sling the Mesh Campaign to the Chair, 20 December 2022](#)

34 IMMDS Review, [First Do No Harm – The report of the Independent Medicines and Medical Devices Safety Review](#) (July 2020), p. 16

35 DHSC, [Government response to the Report of the Independent Medicines and Medical Devices Safety Review](#) (July 2021), p. 75

36 Oral Evidence taken on 13 December 2022, [HC \(2022–23\) 689, Q48–52 \[William Vineall\]](#)

37 [Letter from Maria Caulfield to the Chair, XX January 2023](#)

2023. The IMMDS review team letter sent to us after the session stated that any register of interests must be “validated by the GMC and the register must be open to public scrutiny”, and that the review team was unclear whether the Department agrees.³⁸

26. Section 92 of the Health and Care Act 2022 gives the Secretary of State statutory powers to make regulations to require manufacturers or commercial suppliers of health care products to publish information about payments or other benefits, made or received. Such information can include details on a payments or benefits, the person who provided it and the person who received it.³⁹ This means the Government has the powers to require industry to disclose payments. On setting up the register for payments by industry to clinicians, Mr Vineall told us:

The latest on that is that we have not yet decided what to do, but we are prepared to regulate in this space. We want to make sure that any action that may be taken is proportionate in the impact on life sciences and the production of drugs and drug products.⁴⁰

27. When asked by our Chair whether there was something stopping the Government from moving forward on this, Mr Vineall continued:

No. It is that there is work still to do to decide the way forward and we have not made any decisions yet. I cannot say anything other than that, but I take your point about moving on at pace.⁴¹

28. In their letter, the IMMDS review team called for the registry to be set up, arguing that voluntary disclosure of payments was not sufficient.⁴²

29. We were encouraged to hear that the Government is going ahead with pilots of a register of clinicians' interests, but we are disappointed by the speed at which the Government is acting on this recommendation. We urge the Government to make the arrangements necessary to ensure the register can be set up swiftly, subject to the pilot phase concluding, to prevent further delay.

30. Although the Government has also given itself the powers to set up a register of industry payments to clinicians, no decision has been made yet about how to implement it, and officials were not able to share a plan of when the register would be active. A register would provide transparency and reassurance, and we urge the Government to move at pace to bring in the necessary secondary legislation to set this up.

The Patient Safety Commissioner

31. Recommendation 2 of the IMMDS review was the establishment of a Patient Safety Commissioner. The review envisioned the commissioner as an independent leader to promote the safety of patients with regard to the use of medicines and medical devices, and to promote the importance of the views of patients and other members of the public

38 [Letter from IMMDS review team to the Chair](#), 20 December 2022

39 Health and Care Act 2022, [Section 92](#)

40 Oral Evidence taken on 13 December 2022, [HC \(2022–23\) 689, Q53 \[William Vineall\]](#)

41 Oral Evidence taken on 13 December 2022, [HC \(2022–23\) 689, Q56 \[William Vineall\]](#)

42 [Letter from IMMDS review team to the Chair](#), 20 December 2022

in relation to the safety of medicines and medical devices.⁴³ The Government accepted this recommendation and subsequently amended the Medicines and Medical Devices Bill to establish the Patient Safety Commissioner as an independent role with statutory powers.⁴⁴ In the subsequent Medicines and Medical Devices Act 2021, the core duties of the Patient Safety Commissioner are set out as:

The Commissioner's core duties are to—(a)promote the safety of patients with regard to the use of medicines and medical devices, and (b)promote the importance of the views of patients and other members of the public in relation to the safety of medicines and medical devices.⁴⁵

32. Dr Henrietta Hughes was put forward as the Government's preferred candidate for the role, and on 5 July 2022 we held a pre-appointment hearing.⁴⁶ Following the hearing we endorsed Dr Hughes' appointment but raised concerns that the lack of clearly defined responsibilities of the role, metrics to define success and adequate resource would mean there is a serious risk the role would fail.⁴⁷

33. The Department for Health and Social Care announcement for Dr Hughes' appointment as Patient Safety Commissioner sets out:

Dr Hughes will be an independent point of contact for patients, giving a voice to their concerns to make sure they are heard. She will help the NHS and government better understand what they can do to put patients first, promote the safety of patients, and the importance of the views of patients and other members of the public.⁴⁸

34. Schedule 1 of the Medicines and Medical Devices Act includes provisions regarding the Patient Safety Commissioner, such as the duty of the Commissioner to “prepare and publish a set of principles to govern the way in which the Commissioner will carry out the Commissioner's core duties.”⁴⁹ We would welcome an update from the Patient Safety Commissioner on the progress on this.

35. The Commissioner for Patient Safety (Appointment and Operation) (England) Regulations 2022 were made under the Medicines and Medical Devices Act 2021. These regulations came into force on 29 March 2022 and set out that the Patient Safety Commissioner must publish a Business Plan, which must include the Commissioner's proposed activities and strategic priorities for the period which the Business Plan covers. The Regulations do not stipulate when the Business Plan must be published, only that it should be “as soon as possible after the first Commissioner takes office”.⁵⁰ At the time

43 IMMDS Review, [First Do No Harm – The report of the Independent Medicines and Medical Devices Safety Review](#) (July 2020), p. 10–11

44 DHSC, [Factsheet: Patient Safety Commissioner](#), 25 January 2021

45 Medicines and Medical Devices Act 2021, [Section 1](#)

46 Health and Social Care Committee, [Formal meeting \(oral evidence session\): Pre-appointment hearing for the Government's preferred candidate for the role of Patient Safety Commissioner](#), 5 July 2022

47 The Health and Social Care Committee, First Report of Session 2022–23, [Pre-appointment hearing for the Government's preferred candidate for the role of Patient Safety Commissioner](#), HC 565, para 5–6

48 [“First ever Patient Safety Commissioner appointed”](#), Department for Health and Social Care Press release, 12 July 2022

49 Medicines and Medical Devices Act 2021, [Schedule 1](#)

50 The Commissioner for Patient Safety (Appointment and Operation) (England) Regulations [2022 \(SI 2022/396\)](#)

of publication of this report, Dr Hughes has only been in post for four months and we are therefore not surprised that the Business Plan has not yet been published. We look forward to reviewing it in due course.

36. The same regulations also introduced a duty on the Patient Safety Commissioner to publish Annual reports. The Annual report must include “a summary of the Commissioner’s activities and an analysis of the effectiveness of those activities in relation to the Commissioner’s core duties.”⁵¹ This Annual report will be essential in evaluating impact and work of the Commissioner, and to assess the resource available to the office.

37. During our evidence session on 13 December 2022, we were told that since Dr Hughes started her role in September 2022, she has recruited four members of staff to her office, and further recruitment is ongoing. Baroness Cumberlege argued that recruiting staff to the Patient Safety Commissioner’s office is challenging, as people with the necessary expertise are “quite hard to find”.⁵² It is the duty of the Secretary of State to ensure the Commissioner has the resources necessary. Schedule 1 of the Medicines and Medical Devices Act 2021 sets out that it is within the power of the Secretary of State to provide “provision of financial or other assistance, including staff, accommodation, equipment or other facilities, for the Commissioner”.⁵³

38. During the evidence session we asked Baroness Cumberlege whether the current level of resources available to the Patient Safety Commissioner is sufficient, to which Baroness Cumberlege responded:

No, not now. It obviously has to grow. It has to be a sustainable, expert organisation that is working with patients, working with the healthcare system and working with the regulators. You know the system. It is huge. It is also the private sector and so on. It is an enormous task.⁵⁴

39. The Minister indicated that she had discussed resources “across patient safety” with the Patient Safety Commissioner. According to the Minister the Patient Safety Commissioner had said that she felt she had enough resourcing “at the moment”, and that she had selected a few areas to look at in detail over her “first few months”.⁵⁵ It was not clear to us whether these areas included reviewing possible redress schemes models. As mentioned previously, we look forward to seeing the Commissioner’s first Business Plan which will provide more detail.

40. Although the vision for what the role of Patient Safety Commissioner will achieve is publicised by the Department, no statement of specific assignments or areas of responsibility, have been published yet. As we set out in our report on the pre-appointment hearing with Dr Hughes, metrics for success and clearly defined responsibilities are needed. Only when these are clearly established can resources be adequately assigned. The risk if this is not done is that the maximum benefit to patient safety will not be fully realised. We therefore urge the Secretary of State to ensure that the Patient Safety

51 The Commissioner for Patient Safety (Appointment and Operation) (England) Regulations [2022 \(SI 2022/396\)](#)

52 Oral Evidence taken on 13 December 2022, [HC \(2022–23\) 689, Q34 \[Baroness Cumberlege\]](#)

53 Medicines and Medical Devices Act 2021, [Schedule 1](#)

54 Oral Evidence taken on 13 December 2022, [HC \(2022–23\) 689, Q35 \[Baroness Cumberlege\]](#)

55 Oral Evidence taken on 13 December 2022, [HC \(2022–23\) 689, Q61 \[Maria Caulfield\]](#)

Commissioner's ability to carry out her important role, as her duties and responsibilities become more clearly defined, is not impeded by a lack of resource for and within her office.

Redress and support

41. More needs to be done to provide support for women and children affected by these medical interventions. During our evidence session Kath Sansom argued that the Government had done very little to engage with women who had lived experience of surgical mesh. She also told us that of the three women involved in ultimately setting up specialist mesh centres (as recommended by the IMMDS review), only one had lived experience of mesh. Ms Sansom characterised this as “tokenistic patient engagement”.⁵⁶ Celia Ingham-Clark, Medical Director for Professional Leadership and Medical Workforce, NHS England, stated in a letter to us that the Department conducted extensive consultation with various patient representative groups, such as Sling the Mesh Campaign, in a “draft service specification” ahead of the actual service specification⁵⁷. Regarding the actual service specification, Ms Ingham-Clark states:

The development of the service specification followed NHS England standard methods and the working group included the Specialised Women's Clinical Reference Group patient and public voice representatives who had a generic patient and public voice role rather than a patient with lived experience role. This was standard methodology at the time of service specification development.⁵⁸

42. The service specification for specialised services for women with complications of mesh inserted for urinary incontinence and vaginal prolapse (16 years and above) was published in March 2021.⁵⁹ In her letter, Ms Ingham-Clark states:

The draft service specification was subject to consultation in October 2018 and feedback was received from a number of stakeholders including representatives of Sling the Mesh. Following the initial service specification consultation, NHS England worked with Sling the Mesh and a small group of patients to work through the concerns raised by patients with lived experience. We held an in-person meeting with Sling the Mesh and other patient groups representing patients in May 2019 and followed this up with a series of webinars for women who were unable to join that meeting, which over 160 people registered for. Patient feedback from these meetings helped to further shape the specification, with particular regard to clarity on the difference between full and partial removal, and the make-up of the multi-disciplinary team.⁶⁰

56 Oral Evidence taken on 13 December 2022, [HC \(2022–23\) 689, Q22 \[Kath Sansom\]](#)

57 According to the NHS England website, service specifications are “important in clearly defining the standards of care expected from organisations funded by NHS England to provide specialised care. The specifications have been developed by specialised clinicians, commissioners, expert patients and public health representatives to describe both core and developmental service standards. Core standards are those that all funded providers should be able to demonstrate, with developmental standards being those which may require further changes in practice over time to provide excellence in the field.”

58 [Letter from Celia Ingham-Clark to the Chair](#), 20 December 2022

59 [NHSE, Service specification: Specialised services for women with complications of mesh inserted for urinary incontinence and vaginal prolapse \(16 years and above\)](#), 11 March 2021

60 [Letter from Celia Ingham-Clark to the Chair](#), 16 December 2022

43. The service specification was then delayed awaiting the IMMDS review's report (published in July 2020). As a follow up a webinar with patients was held in September 2020 to see whether any further changes were needed based on the report. According to Ms Ingham-Clark's letter 100 patients registered,⁶¹ but the letter does not disclose how many attended.

44. *We are concerned that although the letter from the Department seems to outline various interactions and consultations with stakeholders, and mentions Sling the Mesh by name, this is not the experience of some patients. Patient input is vital in setting up care schemes such as this one. We therefore urge the Department to reflect on the experience of some of the stakeholders with lived experience in this instance, and to consider how to improve engagement with them in the future.*

45. In addition to providing specialist centres and care pathways, the IMMDS review recommended that those affected should receive financial redress. Recommendation 4 proposed the establishment of three separate schemes, which would meet the cost of providing additional care and support to those who have been avoidably harmed by these three interventions.⁶² In their follow up letter, the IMMDS team called for the Minister to:

[...] make a clear public statement in support of the case for the schemes we recommended, recognising that the victims are suffering lifelong, and in many cases life-changing, consequences through no fault of their own. The healthcare system has let them down. It is not fair that they should have to bear the cost of the adaptations and special support they need. We believe the Minister should recognise that publicly and unequivocally.⁶³

46. In their interim response to the IMMDS Review on 11 January 2021 the Government stated that Recommendation 4 was under consideration.⁶⁴ Six months later in their full response of 21 July 2021, the Government position was:

We do not accept this recommendation. Our priority is to make medicines and devices safer and the government is pursuing a wide range of activity to further this aim.⁶⁵

47. The Government's update on the response, published 12 December 2022, reiterated that the Government did not accept recommendation 4. The update instead pointed to two "claims gateways" on the NHS Resolution (NHSR) website, which the Government argued would provide further support to patients who may wish to bring a clinical negligence claim in relation to pelvic mesh and sodium valproate:

61 [Letter from Celia Ingham-Clark to the Chair](#), 16 December 2022

62 [IMMDS Review, First Do No Harm – The report of the Independent Medicines and Medical Devices Safety Review](#) (July 2020), p. 12

63 [Letter from IMMDS review team to the Chair](#), 20 December 2022

64 [DHSC, Independent Medicines and Medical Devices Safety Review: update report on government implementation](#), 12 December 2022

65 [DHSC, Government response to the Report of the Independent Medicines and Medical Devices Safety Review](#) (July 2021), p. 23

The gateways will make it easier for claimants to initiate a claim by providing all the information they need to do so in a central location and allowing claimants to submit their claim directly to NHSR. NHSR will then arrange for it to be investigated.⁶⁶

48. It is our view that the pathways, which are additional web pages with information for those who would like to bring a clinical negligence claim due to harms caused by these medical interventions, although useful, do not provide a substantial change nor benefit to those seeking to bring claims. The IMMDS Report argued that litigation had not been useful for the majority of those they had heard from who had been affected by the three medical interventions:

We are aware of a handful of successful claims for valproate and mesh against individual doctors, but to date we are not aware of any successful product liability cases against manufacturers of HPTs, valproate or pelvic mesh products in England and Wales.⁶⁷

49. This, to us, indicates that the issue in bringing claims regarding these medical interventions is not due to how or where to submit their claim, but rather that the process itself was not fit for this purpose, and therefore the pathways will have a limited impact. The Government's update admits that the pathways are not a change to the legal framework, but rather a way of making "the process to initiate a claim easier for claimants" and that "claims will continue to be assessed against the normal legal threshold for clinical negligence".⁶⁸

50. Emma Murphy from In-FACT told us during the evidence session:

We have tried the route of clinical negligence against the NHS, and that has failed. Even to suggest that to parents is an insult, and it continues the insult to our families to keep suggesting that and to keep knocking our families back.⁶⁹

51. It is positive that the Government has improved its communication and information online around how to bring claims of clinical negligence through the new "pathways". However, these pathways do not represent a substantial change or benefit to stakeholders who have repeatedly expressed their frustration regarding seeking redress.

52. In the adjournment debate on Fatalities relating to foetal valproate spectrum disorder on 7 December 2022,⁷⁰ and during our oral evidence session on 13 December 2022 the Minister said that she had asked the Patient Safety Commissioner to look at what redress

66 DHSC, [Independent Medicines and Medical Devices Safety Review: update report on government implementation](#), 12 December 2022

67 IMMDS Review, [First Do No Harm – The report of the Independent Medicines and Medical Devices Safety Review](#) (July 2020), p. 27

68 DHSC, [Independent Medicines and Medical Devices Safety Review: update report on government implementation](#), 12 December 2022

69 Oral Evidence taken on 13 December 2022, [HC \(2022–23\) 689, Q20 \[Emma Murphy\]](#)

70 HC Deb, 7 December 2022, [col 471](#) [Commons Chamber]

schemes could look like.⁷¹ In their letter the IMMDS Review team expressed their concerns regarding the Patient Safety Commissioner being given additional responsibilities in addition to her core statutory duties.⁷²

53. *The focus of Patient Safety Commissioner and small team, and must remain, patient safety and harm prevention. If the additional responsibility of reviewing redress is placed on the Patient Safety Commissioner, the Secretary of State must ensure that the Commissioner and her office has access to proper independent expert advice and support. We urge the Secretary of State to make a statement detailing the Patient Safety Commissioner's review of redress schemes for the medical interventions dealt with by the IMMDS review, and what additional resources will be made available to her to undertake it.*

54. Recommendation 3 of the IMMDS review was to set up a Redress Agency to provide redress using a non-adversarial process based on whether avoidable harm had occurred due to systemic failings, instead of placing blame on individuals. Crucially, the IMMDS Review recommendation would not require the person seeking redress to have a legal claim. Rather than replacing legal proceedings and litigation, the IMMDS review envisioned a “stand-alone redress mechanism” which the review argued would be fairer and easier to use:

Obtaining the redress that they are entitled to should not feel like a battle and should not cause further suffering. Litigation is adversarial, but obtaining redress does not have to be. The Redress Agency should operate on the ombudsman model. It will listen to both sides, investigate impartially, and reach a decision. The onus is not on the injured party to prove their case.⁷³

55. In its response to the IMMDS review the Government stated that there were no plans to establish an independent redress agency, arguing that:

We do not believe that a redress agency would make products safer and support our commitment to patient safety. We also believe it is already possible for government and others to provide redress where this is considered necessary, the government therefore has no plans to establish an independent redress agency.⁷⁴

56. During the session William Vineall told us that:

You do not need a redress agency to introduce redress. We run some redress schemes through NHS Resolution. Just the other week, we announced a redress scheme for the victims of David Fuller⁷⁵. There are options within the existing structures to introduce redress, if we wish.⁷⁶

71 Oral Evidence taken on 13 December 2022, [HC \(2022–23\) 689, Q61 \[Maria Caulfield\]](#)

72 DHSC, [Independent Medicines and Medical Devices Safety Review: update report on government implementation](#), 12 December 2022

73 IMMDS Review, [First Do No Harm – The report of the Independent Medicines and Medical Devices Safety Review](#) (July 2020), p. 215

74 DHSC, [Government response to the Report of the Independent Medicines and Medical Devices Safety Review](#) (July 2021), p. 22

75 David Fuller was found in 2021 to have carried out inappropriate and unlawful actions in the mortuary of Maidstone and Tunbridge Wells NHS Trust, as well as other offences.

76 Oral Evidence taken on 13 December 2022, [HC \(2022–23\) 689, Q61 \[William Vineall\]](#)

57. However, in order to bring a claim, NHS Resolution sets out that the claimant must prove, on the balance of probabilities (which means greater than a 50% chance) that there was a breach of duty of the health care provider, and that had the claimant been given additional or different information, they would have chosen to do something different.⁷⁷ For those seeking information about making a claim regarding sodium valproate, the NHS Resolution website also stipulates that the claimant must prove that they suffered damage resulting from the breach of duty of care.⁷⁸ As we argued in our NHS Litigation Reform report, the current NHS clinical negligence system, which requires claimants to prove fault, is fundamentally adversarial. In our report we further concluded that the “defining feature of clinical negligence is the distress it causes for those involved, whether they be defendants or claimants”.⁷⁹ NHS Resolution’s own website states that “making a claim can be an expensive, stressful and potentially a lengthy process.”⁸⁰ During the NHS Litigation Reform inquiry, the Chief Executive of NHS Resolution Helen Vernon told us:

It is important to be clear that we work within a negligence system. That is the law. That is the legal framework within which we have to operate and settle claims. That is how our regulations for operating the indemnity schemes are established as well.⁸¹

58. So far, the Government response to the IMMDS review recommendations which involve redress has been to promote litigation, rather than to consider providing an alternative to it. We have heard from those affected that this approach has not worked for them. These families need support, and they have waited too long. Regardless of whether it is called compensation or redress, NHS Resolution can only make payments where the recipient can show they would win a legal claim for compensation where they prove blame on the part of the healthcare provider. The redress schemes proposed by the IMMDS review are therefore something fundamentally different. During the session Simon Whale, IMMDS Review Member and Communications Lead, described them as follows:

What we are talking about is something different; it is an approach based on redress rather than fighting for compensation. It is based on a no-blame approach rather than a blame approach. Clinical negligence, effectively, requires someone to be blamed and the system closes ranks when that happens, perhaps understandably so. A redress scheme is not about assigning blame. It is about saying, “There has been avoidable harm. People deserve help and they should be given help irrespective of the assignment of blame.” A redress scheme does not mean that individuals who wish to cannot litigate. It would not prevent them from doing so, but it would ensure that they get help and support for their unmet needs. It is quite a different thing from the gateway that has been announced through NHS Resolution. That is still based on a clinical negligence approach.⁸²

59. We were encouraged to hear the Minister say that she was willing to look at the idea of a Redress Agency as well as redress schemes.⁸³ However, the Minister made it clear that

77 NHS Resolution, [Vaginal Mesh](#), accessed 3 January 2022

78 NHS Resolution, [Sodium Valproate](#), accessed 3 January 2022

79 Health and Social Care Committee, Thirteenth Report of Session 2021–22, [NHS litigation reform](#), HC 740

80 NHS Resolution, [Advice For Claimants](#), accessed 3 January 2023

81 Oral evidence taken on 1 February 2022, [HC \(2022–23\) 740](#), Q165 [Helen Vernon]

82 Oral Evidence taken on 13 December 2022, [HC \(2022–23\) 689](#), Q39 [Simon Whale]

83 Oral Evidence taken on 13 December 2022, [HC \(2022–23\) 689](#), Q50 [Maria Caulfield]

this would be following a review by the Patient Safety Commissioner which we have not seen an expected timeline for. In their letter the IMMDS Review Team instead suggested that the Minister conduct an open and objective assessment of the case for such an Agency and publish the findings by the end of June 2023.⁸⁴

60. We would welcome a statement from the Minister on the review of redress and a possible Redress Agency, with more details on what such a review would include and seek to achieve, and timeline for completion.

Conclusions and recommendations

Follow up the IMMDS report and the Government's response

1. *Without records of which patient has undergone which procedure, or been prescribed which drug, the health system will continue to, in the words of the IMMDS review team, “fly blind”. We recommend that the Government urgently ensures that the accepted recommendations 6 and 7 of the IMMDS review are fully implemented. (Paragraph 22)*
2. *Although the retrospective audit of mesh implants is an encouraging first step, it will be unlikely to reflect and take into account all of the adverse effects women have experienced due to the nature of data used in the audit. We therefore recommend that the Government consider an alternative strategy for how to pro-actively contact those who have had the procedure about their post-operative experiences and possible side effects. (Paragraph 23)*
3. *We were encouraged to hear that the Government is going ahead with pilots of a register of clinicians' interests, but we are disappointed by the speed at which the Government is acting on this recommendation. We urge the Government to make the arrangements necessary to ensure the register can be set up swiftly, subject to the pilot phase concluding, to prevent further delay. (Paragraph 29)*
4. *Although the Government has also given itself the powers to set up a register of industry payments to clinicians, no decision has been made yet about how to implement it, and officials were not able to share a plan of when the register would be active. A register would provide transparency and reassurance, and we urge the Government to move at pace to bring in the necessary secondary legislation to set this up. (Paragraph 30)*
5. *Although the vision for what the role of Patient Safety Commissioner will achieve is publicised by the Department, no statement of specific assignments or areas of responsibility, have been published yet. As we set out in our report on the pre-appointment hearing with Dr Hughes, metrics for success and clearly defined responsibilities are needed. Only when these are clearly established can resources be adequately assigned. The risk if this is not done is that the maximum benefit to patient safety will not be fully realised. We therefore urge the Secretary of State to ensure that the Patient Safety Commissioner's ability to carry out her important role, as her duties and responsibilities become more clearly defined, is not impeded by a lack of resource for and within her office. (Paragraph 40)*
6. *We are concerned that although the letter from the Department seems to outline various interactions and consultations with stakeholders, and mentions Sling the Mesh by name, this is not the experience of some patients. Patient input is vital in setting up care schemes such as this one. We therefore urge the Department to reflect on the experience of some of the stakeholders with lived experience in this instance, and to consider how to improve engagement with them in the future. (Paragraph 44)*
7. *It is positive that the Government has improved its communication and information online around how to bring claims of clinical negligence through the*

new “pathways”. However, these pathways do not represent a substantial change or benefit to stakeholders who have repeatedly expressed their frustration regarding seeking redress. (Paragraph 51)

8. *The focus of Patient Safety Commissioner and small team, and must remain, patient safety and harm prevention. If the additional responsibility of reviewing redress is placed on the Patient Safety Commissioner, the Secretary of State must ensure that the Commissioner and her office has access to proper independent expert advice and support. We urge the Secretary of State to make a statement detailing the Patient Safety Commissioner's review of redress schemes for the medical interventions dealt with by the IMMDS review, and what additional resources will be made available to her to undertake it. (Paragraph 53)*
9. *We would welcome a statement from the Minister on the review of redress and a possible Redress Agency, with more details on what such a review would include and seek to achieve, and timeline for completion. (Paragraph 60)*

Formal minutes

Tuesday 17 January 2023

Members present:

Steve Brine, in the Chair

Paul Blomfield

Paul Bristow

Mrs Paulette Hamilton

Dr Caroline Johnson

Rachael Maskell

James Morris

Taiwo Owatemi

Draft Report (*Follow up on the IMMDS report and the Government's response*), proposed by the Chair, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 60 agreed to.

Resolved, That the Report be the Sixth Report of the Committee to the House.

Ordered, That the Chair make the Report to the House.

Ordered, That embargoed copies of the Report be made available, in accordance with the provisions of Standing Order No. 134.

Adjournment

Adjourned till Tuesday 24 January 2023 at 9.30 am

Witnesses

The following witnesses gave evidence. Transcripts can be viewed on the [inquiry publications page](#) of the Committee's website.

Tuesday 13 December 2022

Emma Murphy, Founder, Independent Foetal Anti-Convulsant Trust (In-FACT);
Janet Williams, Founder, Independent Foetal Anti-Convulsant Trust (In-FACT);
Kath Sansom, Campaigner, Sling the Mesh Campaign

[Q1–25](#)

Professor Sir Cyril Chantler, Deputy Chair, Independent Medicines and Medical Devices Safety Review; **Simon Whale**, Review Member and Communications Lead, Independent Medicines and Medical Devices Safety Review; **Baroness Julia Cumberlege**, Chair, Independent Medicines and Medical Devices Safety Review

[Q26–42](#)

Maria Caulfield MP, Parliamentary Under-Secretary of State (Minister for Mental Health and Women's Strategy), Department of Health and Social Care; **Dr Aidan Fowler**, National Director of Patient Safety in England, Department of Health and Social Care; **William Vineall**, Director of NHS Quality, Safety and Investigations, Department of Health and Social Care; **Celia Ingham-Clark**, Medical Director for Professional Leadership and Medical Workforce, Department of Health and Social Care; **Dame June Raine**, Chief Executive, Medicines and Healthcare products Regulatory Agency (MHRA)

[Q43–89](#)

List of Reports from the Committee during the current Parliament

All publications from the Committee are available on the publications page of the Committee's website.

Session 2022–23

Number	Title	Reference
1st	Pre-appointment hearing for the Government's preferred candidate for the role of Patient Safety Commissioner	HC 565
2nd	The impact of body image on mental and physical health	HC 114
3rd	Workforce: recruitment, training and retention in health and social care	HC 115
4th	The future of general practice	HC 113
5th	Pre-appointment hearing with the Government's preferred candidate for the role of Chair of HSSIB	HC 843
1st Special	Cancer Services: Government Response to the Committee's Twelfth Report of 2021–22	HC 345
2nd Special	Government Response to the Expert Panel's Report on Government commitments in the area of cancer services in England	HC 346
3rd Special	Expert Panel: evaluation of Government's commitments in the area of the health and social care workforce in England	HC 112
4th Special	The treatment of autistic people and people with learning disabilities: Government Response to the Committee's Fifth Report of Session 2021–22	HC 631

Session 2021–22

Number	Title	Reference
1st	The Government's White Paper proposals for the reform of Health and Social Care	HC 20
2nd	Workforce burnout and resilience in the NHS and social care	HC 22
3rd	Pre-appointment hearing for the Chair of the Food Standards Agency	HC 232
4th	The safety of maternity services in England	HC 19
5th	The treatment of autistic people and people with learning disabilities	HC 21
6th	Coronavirus: lessons learned to date	HC 92
7th	Supporting people with dementia and their carers	HC 96
8th	Children and young people's mental health	HC 17

Number	Title	Reference
9th	Clearing the backlog caused by the pandemic	HC 599
10th	Pre-appointment hearing for the position of Chair of NHS England	HC 1035
11th	Pre-appointment hearing for the position of Chair of the Care Quality Commission	HC 1091
12th	Cancer services	HC 551
13th	NHS litigation reform	HC 740
1st Special	The Health and Social Care Committee's Expert Panel: Evaluation of the Government's progress against its policy commitments in the area of maternity services in England	HC 18
2nd Special	The Health and Social Care Committee's Expert Panel: Evaluation of the Government's progress against its policy commitments in the area of mental health services in England	HC 612
3rd Special	Supporting people with dementia and their carers: Government Response to the Committee's Seventh Report	HC 1125
4th Special	Expert Panel: evaluation of the Government's commitments in the area of cancer services in England	HC 1025

Session 2019–21

Number	Title	Reference
1st	Appointment of the Chair of NICE	HC 175
2nd	Delivering core NHS and care services during the pandemic and beyond	HC 320
3rd	Social care: funding and workforce	HC 206
4th	Appointment of the National Data Guardian	HC 1311