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Health and Social Care Committee

Government Response to the Committee's Report on Follow-up on the IMMDS report and the Government's response

Fifth Special Report of Session 2022–23

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Health and Social Care Committee

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Fifth Special Report

The Committee published its Sixth Report of Session 2022–23, *Follow-up on the IMMDS report and the Government's response* (HC 689), on 20 January 2023. The Government response was received on 12 April 2023 and is appended below.

Appendix: Government Response

Introduction

This is the Government's formal response to the recommendations made by the Health and Social Care Committee in its report 'Follow-up on the IMMDS report and the Government's response', published on 17 January. The Committee's report and the preceding evidence session on 13 December 2022 focused on the views of those affected by the medicines and medical devices, during which the committee heard powerful accounts. The session also focused on the progress Government is making against the commitments it made in response to the Independent Medicines and Medical Devices Safety (IMMDS) Review.

The IMMDS Review was established to look at how the health system responds when patients and their families raise concerns about the safety of treatments. The review focussed on vaginal mesh, sodium valproate and hormone pregnancy tests and produced a report, published in July 2020, containing nine recommendations and 50 actions for improvement. The review was England-only, yet through continued engagement and collaboration with the Devolved Governments the Department has set about to achieve a UK-wide approach in certain areas with benefits and safety improvement for citizens across the UK.

The Government's response to the review, published in July 2021, accepted the majority of the nine recommendations and the vast majority of the 50 actions for improvement. Effective implementation of the commitments we made in response to the review remains a priority for the Government, and we are making good progress, including the appointment of Dr Henrietta Hughes as England's first Patient Safety Commissioner in 2022.

We have also set out our wider ambitions for women's health in the first ever Women's Health Strategy for England, published in summer 2022. The strategy sets an ambitious agenda for boosting health outcomes for women and girls improving the way in which the health and care system listens to women's voices. The strategy contains the immediate actions we are implementing, including engaging with women and girls, collaborating with experts and researchers, and working with the Women's Health Ambassador, NHS and wider health and care system. The strategy was informed by the nearly 100,000 individual responses to the call for evidence held in 2021. On 24 January 2023, we updated all MPs on the year 1 priorities for implementing the Women's Health Strategy.

Initiatives already in place such as the statutory Duty of Candor, implementing medical examiners, and establishing the Healthcare Safety Investigation Branch to conduct major safety investigations are examples of our commitment to transparency and the development of a learning culture in the NHS so that treatment and care is always

provided to the highest possible standard. This is in addition to the 2019 NHS Patient Safety Strategy being implemented by NHS England, which aims to improve the way the NHS learns from avoidable patient harm and creates a safety culture across the NHS. Achievements include: the launch of the new Learn from Patient Safety Events (LFPSE) and Patient Safety incident Response Framework (PSIRF); publication of the first ever patient safety syllabus offering free online training for all NHS staff; recruitment of Patient safety specialists in all NHS Trusts; publication of the framework for involving patients in patient safety and recruitment of the first Patient safety partners in acute and mental health trusts; new style national patient safety alerts; publication of the first work on patient safety inequalities and the implementation of safety improvement programmes via the patient safety collaboratives.

We welcome the Committee's focus on this area and the evidence and recommendations contained in the report, which is aimed at helping to drive forward further progress to deliver the improvements we all want to see. This document sets out our response to each of the Committee's nine recommendations.

The structure of this memorandum corresponds to the recommendations in the committee's report. The text taken from the Select Committee report is highlighted in bold.

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).

In the Government's response to the IMMDS Review, published in July 2021, we accepted both recommendations 6 and 7 of the Review.

Recommendation 6 covers the Medicines and Healthcare products Regulatory Agency's (MHRA) role in relation to adverse event reporting and medical device regulation, as well as patient engagement. MHRA remains committed to delivering on this recommendation and has over the last two years delivered an ambitious organisation-wide transformation to ensure it becomes a progressive and responsive patient-focused regulator of medical products. It has established a new organisational structure to improve how it listens and responds to patients and the public and has developed a more responsive system for reporting adverse incidents, which will strengthen the evidence to support timely and robust decisions that protect patient safety.

The MHRA's Patient Involvement Strategy, published in October 2021, sets out how they will engage and involve the public and patients at every step of the regulatory journey. Its five strategic objectives include introducing clear processes for public and patient engagement and involvement, as well as embedding the public and patient voice when designing and delivering its services. With these objectives in mind since 2021, the MHRA:

- Have been involving patients in the early stages of medicinal product development and encouraging the wider research landscape to do the same.
- Are incorporating patient views and lived experience in more of our benefit-risk reviews of medical products.

- Developed a more consistent and effective approach to public consultations by introducing an enhanced and user-friendly on-line platform.
- Have launched a training programme on patient involvement, specially designed for our staff and built a network of staff "Patient Involvement Champions".

In addition, over 2,400 members of the public have given their views on a new scheme which will help the MHRA understand and reduce the number of harmful side effects caused by medicines.

MHRA recognise there is more to do to ensure they deliver on their commitment to put patients first, and this is just the start of a journey.

Recommendation 7 of the IMMDS Review calls for a central patient-identifiable database to be created by collecting key details of the implantation of all devices at the time of the operation, to be linked to specifically created registers to research and audit the outcomes both in terms of the device safety and patient reported outcomes measures. Over 2021–2022, NHS Digital undertook a scoping exercise to determine how best to deliver this recommendation. It was concluded that, for England, expanding the coverage and breadth of existing registries will best deliver harmonised data collections that contain patient, device and outcome-level data.

NHS England have, since Summer 2022, commenced the developing of an 'Outcome and Registries Programme' as well as a new 'Medical Device Outcome Registry' (MDOR) and have been working to establish the programme at pace including governance, patient representation, clinical leadership, a technology platform and a coverage roadmap to deliver patient-centred change. The programme will involve a single unified outcome registry platform which will cover the priority medical specialties and therapeutical areas, prioritised according to patient and clinic risk. This aims to deliver on the priorities of traceability and patient outcomes through the enhancement of proven registry processes.

NHSE are working through technical barriers and set to achieve the planned date for platform development in March 2023 with a view to then final testing of the platform and onboard process before launch in April 2023. NHSE is establishing clinical steering boards in the top 10 medical device specialties that account for over 80% of implant usage, to guide the development and implementation of registries and resolve emerging device safety issues. 6 specialty steering boards have been established, with 4 more in progress and a target to having all 10 operational by the end of March 2023 prior to launch of the MDOR platform in April 2023.

The development work for the rapid expansion of the registries has been progressing. This has included the development of a new medical device-level registry platform architecture. NHSE is also in the process of transitioning several existing registries to the new platform. The pelvic floor registry is operational in NHS England and an improved version, integrated with the Outcome Registries platform is in pilot and due for release with the wider platform in May 2023.

The programme is also working to develop an improved model for patient engagement and involvement. There are three levels of patient involvement envisaged for the programme: existing patient involvement in outcome registries, the recruitment of patient

representation onto the Outcome and Registries Programme Board) and the development of a Patient Advisory Group that can provide a point of engagement for diverse patient advocacy groups and charities with the programme.

In parallel, we are working with Devolved Governments to develop a UK-wide approach that will enable secure data sharing, system interoperability and UK-wide coverage, where appropriate to do so.

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).

NHS Digital undertook an audit of all pelvic floor surgery completed between 2006 and 2011 to generate a historical baseline of outcomes by procedure type and to support further research and analysis. The audit captures subsequent procedures and re-operations over a 10-year period after the initial procedure.

This audit was conducted using initial procedures, re-operations and follow up procedures recorded within Hospital Episode Statistics data. The audit is currently undergoing peer review, which may reveal the need for further enhancements, prior to publication by NHS England later in 2023.

In parallel NHS England is working to ensure high-quality data is collected within the specialist mesh centres. In the short-term, a patient questionnaire is being designed and we expect to have it complete by the end of April 2023, which includes both patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs). This questionnaire incorporates the existing pelvic floor PROMs that are in use by clinicians, as well as additional questions that have been requested by clinicians who are treating patients with complications of mesh insertion.

The data collected from the patient questionnaire within the specialist mesh centres will begin feeding into the existing Pelvic Floor Registry, the database that collects surgical device and implant data directly from NHS and private healthcare providers in the UK, in May 2023. When the questionnaire results are fed into the existing registry. Regarding PROMs, we are re-designing the pelvic floor PROM and working towards patient and clinician consultation on the final design by the end of April 2023.

Longer-term, the National Institute for Health and Care Research is commissioning the development of a validated PROM for pelvic floor disorders. The study is expected to start in May 2023. Development, testing, evaluation and validation of a new PROM is likely to take around 3 years and requires patient, clinical and specialist academic input to ensure that the data collected is suitable for outcome-based analysis and evaluation. The study will develop a new questionnaire which will help women to report how surgery for POP, UI and mesh complications has affected their quality of life.

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).

We are currently piloting systems for doctors to declare their interests in NHS and independent settings across the UK, with the aim of achieving consistency in the information collected and made available to patients. Throughout the pilot, we have worked with healthcare providers across different healthcare settings, including primary and secondary care, to assess the feasibility and cost of establishing and maintaining systems for collecting and publishing this information. We have sought feedback from providers, doctors, and patients on the content of standardised templates and guidance, as well as the accessibility of information for patients.

As the healthcare landscapes in the four nations differ significantly, the piloting phase has not progressed at the same pace across the UK. In response to the Committee's comments, we have agreed with Devolved Government officials that rather than wait for all nations to be in a position to move into the implementation phase, we will progress at different paces. We expect the implementation phase to begin in England in April 2023. We will continue to work with the Devolved Governments to ensure consistency in approaches across the UK.

There will be a lead-in time of approximately 18 months, before the CQC begin to monitor publications of interests on organisations' websites in England.

Once we have established a system in place for doctors, we will consider systems for other healthcare professionals.

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).

Work is now underway on the reporting of payments and other benefits made to healthcare organisations, individual clinicians, and linked recipients, including medical charities, professional bodies, and research institutions. We aim to launch a six-week public consultation in Spring 2023 to seek public and industry views on the potential to introduce regulations mandating the reporting of such payments and benefits.

Work is also proceeding to determine the enforcement regime that would be required should regulations be introduced. The policy in this area is devolved but we have reached agreement with Scotland, Wales and Northern Ireland to run a UK-wide consultation. Any regulations which follow the public consultation will operate across the whole of the UK and will require consent from the Scottish Parliament, the Welsh Senedd and the Northern Ireland Assembly.

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).

We are pleased to have appointed Dr Henrietta Hughes as England's first ever Patient Safety Commissioner, and she began work in earnest in September 2022. The Commissioner has statutory powers to act as a champion for patients, alongside a core role of promoting the safety and views of patients and the public in relation to medicines and medical devices.

The Commissioner published a 100 Days Report on 2 February that sets out progress to date including engagement with patient groups and health leaders to ensure issues of redress and safe medication are upmost in the minds of regulators and health leaders. The Patient Safety Commissioner also outlined her top three priorities of culture change, pelvic mesh complications and sodium valproate.

The Department continues to work with Commissioner, including on appropriate levels of resource, now the shape of the work and the role is taking shape. We will report back to the Committee once these discussions have concluded.

The Commissioner will publish her business plan in good time once the Patient Safety Commissioner website is complete and functional.

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).

In the Government's December 2022 IMMDS Review update, we committed to work with NHS England to review mesh centre outcomes and patient experience.

In March 2023 Minister Caulfield met with some mesh campaigners and NHS England to discuss plans for the audit of specialist mesh centres.

The NHS England Specialised Women's Services Clinical Reference Group will provide governance for the mesh centre audit. Paula Goss (Rectopexy Mesh Victims and Support) and Kath Sansom (Sling the Mesh) agreed to join the Clinical Reference Group as Patient and Public Voice Members to ensure patient voice is considered throughout the audit. The audit is due to take place in 2023.

Patient engagement has been a core component of the NHS England commissioning and service implementation activities for Mesh Centres. For example:

- To ensure that the specialist centres are supporting women with complications of pelvic mesh as intended, DHSC will work with NHSE to review mesh centre outcomes and patient experience. This audit of mesh centres will start later this year.

- To improve care for women with pelvic floor health issues nationally, NHS England and NHS Improvement established a 'Pelvic Floor Health Oversight Group' in August 2019, which drew on both patient and clinical expertise.

- The NHS England specialised commissioning team worked with the IMMDS Review team to review and update the service specification against the Review's interim and final findings. The review of the service specification was carried out with the involvement of patient stakeholders, in September 2020, ahead of the procurement of the mesh centres. This service specification was included in the procurement process for the centres.

- In March 2021 the NIHR commissioned a £500,000 research study on 'Women's Experiences of Urogynaecological services', which will inform work to establish a new validated PROM for pelvic floor (mesh and related procedures) and report by June 2023. Recognising the need for rapid progress in this area, the NHS England Registry Team (previously part of NHS Digital) started work in started work on the study in March 2021 with patient groups and clinicians to develop a new unvalidated PROM to develop a new questionnaire which will help women to report how surgery for POP, UI and mesh complications has affected their quality of life , which will be used alongside existing validated PROMs in the interim until a new validated PROM for pelvic floor is developed.

- Mesh Centres were asked to mobilise and establish the service in line with the service specification in April 2021. In May 2022, the Women and Children's Specialised Services National Programme of Care Lead in NHS England held engagement meetings with all 9 Mesh Centres, supported by patient and public voice representatives. The engagement meetings were designed to explore how the new services are progressing, to hear about their experience of delivering care in line with the service specification and to enable an update to be provided to the Department of Health and Social Care outlining progress against the recommendations set by the First Do No Harm report. Findings of the engagement meetings included:

  - All of the centres reported that they had in place systems and process for helping patients to navigate pathways and to support their patient experience and journey, with this support provided either directly through specialist nurse teams or through their dedicated Mesh Pathway Coordinator.

  - 6 of the 8 Mesh centres either already had or were planning to bring in Patient Forums as part of the Mesh centre development.

- All specialised services for women with complications of mesh must meet annually at a Clinical Summit to present data and discuss outcomes. At the inaugural clinical summit held in December 2022 chaired by Dr Terry Okelly [Colorectal Surgeon and Senior Medical Officer NHS Scotland], sessions included reflections on patient experience, lessons for the future and feedback from patients who have been treated by the NHS England Mesh Centres. The Clinical Summit included Sling the Mesh representation and Baroness Julia Cumberlege also attended.

- As a result of the summit, and feedback from the Department of Health and Social Care following meetings with Ministers and the Patient Safety Commissioner, NHS England through the Specialised Women's Clinical Reference Group [Chaired by Dr Janice Rymer, Prof of Obstetrics and Gynaecology and National Speciality Advisor for Gynaecology and Specialised Women's Clinical Reference Group], NHS England has put in place arrangements:
  - To develop an audit tool and audit programme for Mesh Centres to enable feedback on information about the overall mesh patient experience as well as updates about patient activity and referral patterns data.
  - Review the arrangements that the Mesh Centres are developing and putting in place for patient engagement and to support service improvement.
  - To review how individual Trusts are working with General Practitioners to support better engagement with the Mesh Complications Programme for referring patients to specialised Mesh Services.
  - Review the Service Specification for patients with complications of mesh inserted for urinary incontinence and vaginal prolapse with a view to developing standards for non-surgical treatment options.
  - Review how the Mesh Centres can engage in joined up training programmes and collaborative research, including putting in place arrangements to support all surgeons to engage with the Mesh Complications Management Training Pathway [The pathway is described here (https://www.rcog.org.uk/careers-and-training/training/curriculum/mesh-complications-management-training-pathway-pilot/) and includes a process of phased implementation and in the absence of a GMC authorised credential.

The Patient Safety Commissioner's 100 days report said that the PSC would co-produce resources for patients and GPs about side effects from pelvic mesh surgery; work with NHS England to enable choice of access to mesh centres; and work with the wider health system to ensure information is available to patients from national registries.

To ensure that the specialist centres are supporting women with complications of pelvic mesh as intended, the Department will continue to work with NHS England to review mesh centre outcomes and patient experience.

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).

We recognise there can be challenges for people to bring clinical negligence claims. One of the challenges identified for those affected by pelvic mesh and sodium valproate was accessing the information they need when considering whether and how to bring a legal claim. We listened carefully to these concerns and worked with NHS Resolution to establish the claims gateways for those affected by pelvic mesh and sodium valproate.

The gateways are designed to make it easier for people to bring a claim by:

- Providing access to the information they need in one place. The gateways set out details of the procedure for reporting and investigating claims and provide an overview of the legal test of negligence and what needs to be established for a successful claim.
- Providing a simplified process for claims to be reported to NHS Resolution which can enable the investigation of a claim to be initiated sooner.
- Enabling and supporting those claimants without legal representation to bring a claim, but also signposting to sources of independent legal advice, which claimants can access if they need it.

NHS Resolution has so far received 16 new claims through the gateways. Investigations have been initiated into all of these claims, but it is too early for any of them to have reached a conclusion resulting in compensation being paid. We will continue to monitor the operation of the gateway and work with NHSR to respond to any learning from its implementation.

8. ***The focus of Patient Safety Commissioner and small team, 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).

Our sympathies remain with all those harmed by medical interventions, including those harmed by sodium valproate and pelvic mesh.

A specification of the redress work has been shared with the Patient Safety Commissioner. This work is intended to cover what form redress could take for people harmed by sodium valproate and pelvic mesh; two of the three interventions covered in the IMMDS review. It is intended to focus on the views of those affected, improving the understanding of how many people have been affected and how, the case for redress and what form it could take.

The work is expected to take around four months and the Patient Safety Commissioner will publish a report of the findings. Following receipt of this report, the Department will need to consider its findings. The Department has agreed additional resources with the Patient Safety Commissioner to support this work.

The Department set out its position on introducing a redress agency in its response to the IMMDS review report in July 2021. In summary, we do not believe it is necessary to create a new agency for redress as it is already possible for the Government and others to provide redress for specific issues where that is considered necessary.