Department of Health & Social Care

Government response to the Report of the Independent Medicines and Medical Devices Safety Review

Published 26 July 2021

ContentsMinisterial foreword 3

Ministerial foreword

The title of the Report – “First Do No Harm” – speaks to a rightful expectation at the heart of our healthcare system: that we avoid harm and protect patients. Our faith in the system depends not only on upholding that expectation but listening and learning when we fail to do so.

The Review was commissioned because the government recognised and accepted that it had taken too long for patients to be listened to. Every single page in the Report makes for harrowing reading; but we must learn from it, and act on it.

That we have this powerful report is a tribute to so many. First, to Baroness Cumberlege and her team for their diligence, dedication and determination to get to the truth – taking the brave testimonies of over 700 people. Equally, we owe a debt of gratitude to the tireless campaigners, including the victims themselves, their families, Members of Parliament and many others.

In the Minister of State's statement in Parliament the day after the report was published, the government apologised unreservedly for the time taken to listen and respond to patients' concerns, and committed to learning from the Report's findings.

We are also enormously grateful to those who have supported the government in our consideration of the Report’s recommendations since. Many of the recommendations discussed in detail during the Lords Committee stage of the Medicines and Medical Devices Act have helped us determine our future direction. The expertise of the All-Party Parliamentary Group ‘First Do No Harm’ has also been invaluable.

I would like to thank all those who have supported work to consider the Report’s recommendations. Many of the recommendations were discussed in detail during the Lords Committee stage of the Medicines and Medical Devices Act, which helped us to determine our future direction. The All-Party Parliamentary Group ‘First Do No Harm’ has also been most helpful in providing continued expertise to inform our thinking as the response work has developed.

In January 2021, we established a Patient Reference Group—as recommended by the Report—to ensure that as we developed the full government response, we listened to the patient's voices. The group met with officials regularly and with the Minister of State in June, and discussions with the group have helped shape the government's response to the Report's recommendations. The Group's commitment to improving patient safety has been inspiring, and we are deeply grateful to group members for retelling their personal stories and sharing their expertise with officials and with Ministers.

The Report also highlights the inequity that has tainted our system for too long: the difference in how the health system works for men and women – and the terrible consequences when we fail to listen to women's voices.

We cannot ignore the fact that this report is one of several independent reports and inquiries to have concluded that our healthcare system disproportionately fails to listen to women and keep them safe. This government is determined to change this, not least through our work to develop the first ever Women's Health Strategy for England.

This Report is a powerful call to action, and we are determined to deliver meaningful change through this government response. We have accepted the majority of the Report's 9 strategic recommendations and 50 Actions for Improvement.

This country, rightly, has great faith in our healthcare system. It's a faith we must constantly strive to deserve. There is always more we can do – and we will do it. We owe it to the women and their families who have been impacted, and the country at large, to make sure we learn the lessons and get everyone the care and protection they deserve.

The Rt Hon Sajid Javid MP

Nadine Dorries MP

1. Introduction

Background to the Independent Medicines and Medical Devices Safety Review

1.1 In February 2018, the then Secretary of State for Health and Social Care, Jeremy Hunt, asked Baroness Julia Cumberlege to lead an independent review into how the health system in England responds to reports from patients about side effects from treatments. Baroness Cumberlege was asked to consider:

- whether any further action is needed relating to the complaints around Primodos, sodium valproate and vaginal mesh;
- the processes followed by the NHS and its regulators when patients report a problem; and
- how to make sure communication between the different groups involved is good

1.2 The Independent Medicines and Medical Devices Safety Review (The Review) team established their own terms of reference for the review, which can be found annexed to the Report of the IMMDS Review. As part of their evidence gathering, the Review team met with over 700 people, mostly women, to listen to their experiences and understand where improvements needed to be made. Whilst the scope of the review was England only, the Review team also met with and listened to patients and patient groups in Scotland, Wales and Northern Ireland.

The report, and an apology

1.3 The Report of the IMMDS Review ('the Report') was published on 8 July 2020, marking the culmination of over 2 years of intense work and dedication by the Review Team.

1.4 **Recommendation 1 of the Report states:** *'The government should immediately issue a fulsome apology on behalf of the healthcare system to the families affected by Primodos, sodium valproate and pelvic mesh'.*

Government response: We accept this recommendation. On 9 July 2020, the day after publication of the Review, the government issued an unreserved apology on behalf of the

healthcare system to those women, their children and their families for the time the system took to listen and respond.

1.5 The government also thanked every single person who contributed to the review, including Baroness Cumberlege and the Review team, those who gave written and oral evidence to the review, and most importantly, the patients who bravely shared their testimonies. In the statement of 9 July 2020, the government committed to learning from this landmark review. It has been imperative, for the sake of patients and especially those who have suffered greatly, for this Report to be given the full consideration it deserves.

The interim response - January 2021

1.6 In our interim response, via the Written Ministerial Statement of 11 January 2021 we announced that:

- we had tabled an amendment to the Medicines and Medical Devices Bill (now the Medicines and Medical Devices Act 2021), to establish a Patient Safety Commissioner, and to create the power to establish a Medical Device Information System (Recommendation 2)
- work was progressing well to establish the specialist mesh services, with an announcement on the locations of the services expected shortly after the Statement was published (Recommendation 5)
- the Medicines and Healthcare products Regulatory Agency (the MHRA) had commenced a substantial reform programme, including work to improve the safety of sodium valproate and other medications taken in pregnancy; (Recommendation 6)
- we would be establishing a Patient Reference Group to work with the government to develop the full response (Recommendation 9)
- we had no plans to establish an independent Redress Agency (Recommendation 3)

1.7 The details of what we have done since January is covered in the body of the report. The pivotal recommendation in shaping our work since January was the establishment of the Patient Reference Group (recommendation 9), which has influenced our response since then.

The Patient Reference Group

1.8 We established the Patient Reference Group (the 'Group') to ensure that patient voices were heard as we developed this response. The Group was made up of patients and patients' representatives, including those involved in the Review and those with a wider interest in patient safety. The Group has been invaluable in providing challenge, scrutiny and advice. Discussions with the group have helped shape the government response to the Report's recommendation, and the expertise and insights from the Group have been integral to ensuring that at every stage the response has taken patient views into consideration. Chapter 2 of this response starts with this work, reflecting the Group's important role in informing the government response.

The government's response to the Report

1.9 The government has considered each of the Report's 9 strategic recommendations and the 50 Actions for Improvement in great depth. The Report sets out a comprehensive timeline of events for each of the 3 interventions, and it would do a disservice to the Review team's incredibly detailed work to attempt to detail this once again. This response therefore focusses on the actions being taken in response to the Report's recommendations. The main recommendations are presented thematically, alongside the corresponding Actions for Improvement, to provide a full and cohesive response to each of the key issues raised by Baroness Cumberlege.

1.10 The government fully accepts the overarching conclusion that the system failed to listen to patients, or to put patients at the centre of their care. We have accepted four of the nine strategic recommendations in full, one in principle and two in part. We have also accepted 46 of the 50 Actions for Improvement in full or in principle, one in part and one remains under consideration. We do not accept two of the Actions for Improvement.

Summary of the government response to each of the Report's recommendations

Recommendation 1: *'The government should immediately issue a fulsome apology on behalf of the healthcare system to the families affected by Primodos, sodium valproate and pelvic mesh.'*

Government response – accept. On 9 July 2020, the day after publication of the Review, the government issued an unreserved apology on behalf of the healthcare system to the

women affected, as well as their children and their families, for the time the system took to listen and respond.

Recommendation 2: *'The appointment of a Patient Safety Commissioner who would be an independent public leader with a statutory responsibility. The Commissioner would champion the value of listening to patients and promoting users' perspectives in seeking improvements to patient safety around the use of medicines and medical devices.'*

Government response – accept. We have legislated for a Patient Safety Commissioner through the Medicines and Medical Devices Act 2021. The Patient Safety Commissioner will act as a champion for patients in relation to medicines and medical devices, adding to and enhancing the existing work described above. We are now consulting on the proposed legislative details that will govern the Commissioner's appointment and operation.

Recommendation 3: *'A new independent Redress Agency for those harmed by medicines and medical devices should be created based on models operating effectively in other countries. The Redress Agency will administer decisions using a non-adversarial process with determinations based on avoidable harm looking at systemic failings, rather than blaming individuals.'*

Government response – do not accept. We have no plans to establish an independent redress agency.

Recommendation 4: *'Separate schemes should be set up for each intervention - HPTs, valproate and pelvic mesh - to meet the cost of providing additional care and support to those who have experienced avoidable harm and are eligible to claim.'*

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

Recommendation 5: *'Networks of specialist centres should be set up to provide comprehensive treatment, care and advice for those affected by implanted mesh; and separately for those adversely affected by medications taken during pregnancy.'*

Government response – accept in part. NHS England and Improvement has led work to establish specialist mesh services. There are now 8 specialist centres in operation. Regarding specialist centres for those adversely affected by medicines taken during pregnancy, the government's view is that a network of new specialist centres is not the most effective way forward. We will in instead take forward work to improve the care pathways for children and families adversely affected by other medicines in pregnancy. On valproate specifically, we are taking forward significant work to ensure that valproate is only prescribed where clinically appropriate.

Recommendation 6: *'The Medicines and Healthcare products Regulatory Agency (MHRA) needs substantial revision particularly in relation to adverse event reporting and medical device regulation. It needs to ensure that it engages more with patients and their outcomes. It needs to raise awareness of its public protection roles and to ensure that patients have an integral role in its work.'*

Government response – accept. The MHRA, reflecting its corporate Delivery Plan for 2021-2023 "Putting patients first - A new era for our Agency", has initiated a substantial programme of work to improve how it listens and responds to patients and the public, to develop a more responsive system for reporting adverse incidents, and to strengthen the evidence to support timely and robust decisions that protect patient safety.

Recommendation 7: *'A central patient-identifiable database should be created by collecting key details of the implantation of all devices at the time of the operation. This can be linked to specifically created registers to research and audit the outcomes both in terms of the device safety and patient reported outcomes measures.'*

Government response – accept. We have already legislated for this through the Medicines and Medical Devices Act 2021, which creates a power for the Secretary of State to regulate for the establishment of a UK-wide Medical Device Information System (MDIS). Alongside developing regulations, over £11m has been set-aside for a package of work in 2021/22 involving partners across the healthcare system to scope, test and cost options for MDIS and other medical devices patient safety workstreams, as well as complete a business case for a 5-year programme of work

Recommendation 8: *'Transparency of payments made to clinicians needs to improve. The register of the General Medical Council (GMC) should be expanded to include a list of financial and non-pecuniary interests for all doctors, as well as doctors' particular clinical interests and their recognised and accredited specialisms. In addition, there should be mandatory reporting for the pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions and individual clinicians.'*

Government response – accept in principle. 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**.** Regarding industry reporting, we agree with the need for greater transparency and we are exploring options to expand and reinforce current schemes.

Recommendation 9: *'The government should immediately set up a task force to implement this Review's recommendations. Its first task should be to set out a timeline for their implementation.'*

Government response – accept in part. We have no current plans to establish an independent task force to implement the government response. We established a Patient Reference Group to work with the government to develop this response.

Actions for improvement

1.11 We have accepted 46 of the 50 Actions for Improvement in full or in principle, one in part and one remains under consideration. We do not accept two of the Actions for Improvement. For further detail on each of the 50 Actions for Improvement, please refer to Annex A on p91.

Conclusion

1.12 This response sets out an ambitious programme of change, which at its core is about improving patient safety by:

- improving how the system listens to and responds to concerns raised by patients by putting patient voice at the centre of patient safety
- strengthening the evidence base on which decisions are made, including through making sure the right data is collected and used
- improving the safety of medicines and devices, and embracing the new opportunities following the UK's departure from the European Union to reform regulatory frameworks

1.13 The actions set out in this response are a combination of well-established programmes of work and new initiatives. The government is committed to making rapid progress on all of the areas set out in this response, and we will aim to publish an update on progress to implement the government response in 12 months' time.

2. Putting patient voice at the centre of patient safety

2.1 One of the key conclusions from the Report was that 'the system has not been listening as it should', and that patients have 'lost trust in those in positions of authority whether it be the medical profession or those responsible for delivering our healthcare services'.

Patient voice

2.2 **Recommendation 9 of the Report states that:** *'The Government should immediately set up a task force to implement this Review's recommendations. Its first task should be to set out a timeline for their implementation […] supporting the implementation process should be a reference group made up of a range of patient interests, going far wider than the groups we have been privileged to work with'.*

Government response: We accept this recommendation in part. We established a Patient Reference Group, which worked with us to develop the government response. The first part of recommendation 9 – a task force to implement this review's recommendations – is addressed in chapter 10 on implementation and next steps. We do not accept this part of the recommendation, and the government has no plans to establish an independent task force to implement the government response.

2.3 The government recognised the need for effective patient engagement in order to rebuild trust and ensure that the patient voice was embedded throughout the immediate task of developing the government response to the Review. We were therefore pleased to announce via the Written Ministerial Statement of 11 January 2021 the establishment of the Patient Reference Group ('the Group').

2.4 The purpose of the Group was to provide challenge, advice and scrutiny to the work to develop the government's response to the recommendations set out in the Report of the IMMDS Review. To ensure that the Group had autonomy and could effectively challenge emerging policy thinking, the Group was recruited and then facilitated by an independent organisation, Traverse. Traverse were appointed by DHSC through an open and competitive tender process.

2.5 Traverse led an open and competitive recruitment process for Group members, with the opportunity being advertised online and distributed through various networks, including by the First Do No Harm APPG. The criteria for membership

was set out in the recruitment pack made available to all applications and included:

- "have a personal experience or understand the context of the Review and the content of the report from the perspective of patients, carers or families
- are committed to improving the experience of patients
- want to engage with others on the group and representatives of the Department to support the implementation of the Review
- can consider complex and emotive issues in a balanced and sensitive way; and
- have good communication skills and want to build strong working relationships with the rest of the group"

2.6 The Group was made up of 14 individuals from across England, including those who have been affected by or have an interest in pelvic mesh, sodium valproate, and Hormone Pregnancy Tests (HPTs), those who have been affected by or have an interest in other medicines or medical devices, and also those with a wider interest in patient safety. Group members were appointed as individuals, not as representatives of patient groups or other organisations. The Group was also chaired by a patient representative, who was elected by Group members.

2.7 As recommended in the Report, group members worked with Traverse to co-develop the Group's Terms of Reference, which ensured that the Group's purpose was grounded in patients' priorities.

2.8 The Group met regularly and worked closely with officials in DHSC, NHS England and Improvement (NHSEI), NHS Digital, NHSX and the MHRA to discuss the Report's recommendations in detail. In each meeting, officials presented an update on progress to consider a recommendation. This was followed by questions from the group and breakout discussions to discuss issues in more depth. The feedback from the Group then informed the final response to the recommendations. Additionally, the Minister of State Nadine Dorries MP met with the Group in June 2021, to listen to feedback from the Group.

2.9 Transparency was of paramount importance to the Group and summaries of each meeting were published on a dedicated page on the Traverse website. To ensure group members were fully supported during the process, they were given access to a free counselling service hosted by Victim Support. Further details of the Group including the recruitment process, membership, terms of reference, the schedule

of meetings and key points raised by the Group can be found in the Independent Report of the Patient Reference Group.

2.10 The Group as a whole, and the individuals on it, have been invaluable in shaping the government's response to the Report. We are extremely grateful to group members for partaking in difficult discussions and we recognise the emotional burden of re-sharing experiences and reflections. The government response has undoubtedly been strengthened through listening to and learning from group members' experiences, knowledge and expertise. It is our desire that this work serves as a blueprint for future work between patients and decision makers to ensure that the patient voice is always at the heart of patient safety.

The Patient Safety Commissioner

2.11 **Recommendation 2 of the Report states:** *'The appointment of a Patient Safety Commissioner who would be an independent public leader with a statutory responsibility. The Commissioner would champion the value of listening to patients and promoting users' perspectives in seeking improvements to patient safety around the use of medicines and medical devices'.*

Government response: We accept this recommendation and have legislated for a Patient Safety Commissioner through the Medicines and Medical Devices Act 2021.The Patient Safety Commissioner will act as a champion for patients in relation to medicines and medical devices, adding to and enhancing the existing work described above. We are now consulting on the proposed legislative details that will govern the Commissioner's appointment and operation.

2.12 The government believes that patient voice must be central to everything the healthcare system does. In 2018, the former Secretary of State for Health and Social Care asked the new National Director of Patient Safety, Dr Aidan Fowler, to develop a ten-year strategy for patient safety. The NHS National Patient Safety Strategy (the Strategy) was published by NHSEI in July 2019. and seeks to significantly improve the way the NHS learns, treats staff and involves patients and support the creation of a safety and learning culture across the NHS.

2.13 A key initiative from the Strategy is the planned publication in 2021/22 of a new Framework for Involving Patients in Patient Safety. This will set expectations to NHS organisations for ensuring patients contribute to both their own safety and the safety of NHS services.

2.14 In addition, this year, we have established a new Patient Safety Programme Board, co-chaired by Minister of State for Patient Safety, Suicide Prevention and

Mental Health to strengthen oversight and governance of measures to improve patient safety.

2.15 We plan to have the first Patient Safety Commissioner in post in 2022. It is integral that patients are listened to in our healthcare system and the Commissioner will help to make sure patient voices are heard, as envisaged in the Report.

2.16 A public consultation on the proposed legislative details that will govern the appointment and operation of the Commissioner was required by the MMD Act. This consultation launched on 10 June 2021 runs until the 5 August 2021. The consultation seeks views from interested parties and the public on the proposed legislative details on the appointment and operation of the Commissioner. The proposals cover a range of topics, including for example, the terms of office for the role, remuneration and funding and the establishment of an advisory panel to support the Commissioner.

2.17 The core role of the Commissioner will be to promote the safety of patients in the context of the use of medicines and medical devices and to promote the importance of the views of patients and other members of the public in relation to the safety of medicines and medical devices. The Commissioner has a number of a statutory powers to help them fulfil their core role. This includes the power to request and share information with relevant persons and the power to make reports or recommendations to relevant persons.

2.18 The Commissioner will be provider neutral, and able to exercise these powers in relation to both the NHS and independent sector. These powers will help to ensure that the Commissioner is a valuable and useful addition to our healthcare landscape.

2.19 We presented an update to the Patient Reference Group in June this year of the progress of the Patient Safety Commissioner and the public consultation. The group provided feedback that centred around the independence of the Commissioner, the transparency of the appointment process, and the efficacy of the Commissioner's powers. This feedback will be considered along with feedback received from the public consultation on the proposed legislative details that will govern the appointment and operation of the Commissioner.

Next steps

2.20 After the consultation has closed, responses received will be carefully considered and reviewed and will feed into the drafting of the regulations on the appointment and operation of the Commissioner.

2.21 A campaign to fill the Commissioner position is also due to be launched later this year, in line with the public appointments process. We expect to appoint the Commissioner in early 2022.

Actions for improvement

Regulation

2.22 There are a number of Actions for Improvement in the Report that relate to regulation. One action proposed in the Report relates to the operation of the Patient Safety Commissioner, set out below

Action for Improvement	Government response
We recommend the creation of a system-wide healthcare intelligence unit to facilitate early signal detection which would draw on various sources of information, including issues raised by the patient safety commissioner.	**Accept in principle.** The government understands the significance of early signal detection and welcomes the emphasis placed on it in the Report. We acknowledge how the role of a system-wide healthcare intelligence unit could safeguard the interests of patients and other members of the public. **Next steps:** will look into this matter further in collaboration with other system wide healthcare bodies.

Informed consent

2.23 The Report acknowledges that consent is at the heart of the patient-clinician relationship, and that listening to patients is essential for effective shared decision-making around future care and treatment. The NHS Long Term Plan states personalised care will become 'business as usual' across the healthcare system, and Universal personalised are: Implementing the Comprehensive Model sets out how the NHS in England will deliver this by 2023/24. Shared decision making is one of the key components of universal personalised care.

2.24 The Report contains 3 Actions for Improvement related to informed consent, set out below:

Action for Improvement	Government response
Information should be conveyed to patients in a way that is clear and meaningful. The opportunity to speak to, or hear from, others who have undergone the same	**Accept.** The General Medical Council's (GMC) revised guidance on 'Decision making and consent' came into effect on 9 November 2020. This makes clear that

Action for Improvement	Government response
intervention should be considered.	serious harm can result from patients not being listened to or not being given relevant information by doctors. The guidance encourages doctors to be open with their patients about uncertainties, to answer questions honestly and to share all relevant information with patients about potential benefits and harms of treatment options so they can make informed decisions about their care. The guidance further advises doctors to consider talking to patients about other sources of information including expert patient programmes and support groups. **Next steps:** in line with the revised guidance, the GMC is creating a patient-facing page on its website to highlight its expectations of doctors. This page will be live by the summer of 2021. This page will also signpost to materials that support patients to have better conversations with doctors. In addition to the GMC, all 9 other healthcare professional regulators have clear guidance on decision making and consent in their codes and standards. All other professional regulators will consider this action for improvement when they next review their guidance.
A single patient decision aid (or core set of information) should be produced for each surgical procedure or medical intervention, co-designed by patients and clinicians. The National Institute for Health and Care Excellence (NICE) should take the lead on facilitating this.	**Accept in principle.** NICE have recently published a new shared decision making guideline (NG197). This guideline covers how to make shared decision making part of everyday care in all healthcare settings. In addition, NHSEI have commissioned NICE to develop a set of standards for the UK for tools that support shared decision making, which will include Patient Decision Aids (PDAs). This work is part of an ongoing project, which involves collaboration between teams from NICE and an oversight group of external shared

Action for Improvement	Government response
	decision-making experts. **Next steps:** NICE is considering how it might take a lead in collaborating with the health system on the production of PDAs for all surgical procedures or medical interventions. This is a potentially complex and resource intensive task. NICE will need to carefully consider the methods used to produce each PDA, its quality assurance, how it is optimally presented and how best it might be validated.
Patient-clinician consultations about consent must be proportionate to the circumstance and appropriately documented. Both the patient's and clinician's concerns and comments should be recorded. Where appropriate and with the agreement of both parties, conversations around consent should be audio or video recorded to allow the patient to take it away and reflect upon it. In future a copy of this discussion should be stored on the patient's electronic record.	**Accept.** The GMC's revised guidance on decision making and consent states that doctors should take a proportionate approach to the level of detail they record about decision making and consent. The guidance also stipulates that, if necessary, patients should be given the time and opportunity to consider any information before making a decision about their treatment and/or care. The guidance advises doctors to record a summary of discussions with a patient, to be made available both to the patient and those involved in their care, and make sure that when a patient gives consent, this is recorded in their notes. The guidance states that doctors should accommodate a patient's wishes if they would like to record the discussion themselves. Any recording made by the healthcare provider as part of a patient's care should form part of the patient's medical record. It is important to note that recordings made by a patient themselves do not have to be stored as part of their medical record. The GMC have provided specific guidance on "Making and using visual and audio recordings of patients". This guidance clearly outlines the principles clinicians should adhere to when making or using visual and audio recordings of patients. The GMC is working with organisations

Action for Improvement	Government response
	across the UK's health services to support doctors to embed this guidance into their everyday practice. This includes collaboration with the Professional Records Standards Body to develop an information record standard for consent and shared decision making that is consistent and effective across the UK.

Complaints

2.25 The Report concludes that '*Patients struggle to navigate the complaints system and it may take some time to find the correct organisation to complain to'*. The government is committed to improving the way the NHS listens to the concerns raised by patients and improving the patient experience.

2.26 The Report contains 4 Actions for Improvement related to complaints, set out below:

Action for Improvement	**Government response**
Patients across the NHS and private sector must have a clear, well publicised route to raise their concerns about aspects of their experiences in the healthcare system. It will be for the implementation task force (see Recommendation 9) to address this problem	**Accept.** The government recognises how important patient feedback is to improving the safety and quality of NHS services and we remain committed to increasing the impact of the voice of patients. Once appointed, the Patient Safety Commissioner will be an important advocate for patients in relation to medicines and medical devices. In addition, DHSC is developing a Patient Safety Action Plan, which will set out a specific set of actions for improving the way the NHS responds to complaints and concerns. The GMC have introduced a number of steps to improve how it supports complainants, including the creation of a Patient Liaison Service, established to improve communications while the GMC are investigating their concerns. In their meetings with complainants, the GMC explains how it is undertaking the investigation relating to their concerns and then informs them of their decisions. In

Action for Improvement	Government response
	addition, through its' Better Signposting programme, the GMC can support complainants, whose concerns would be better directed to another organisation, to find the right place for their complaint. The GMC have revised their online directory of help for complainants and have updated their online complaint form and signposting decision tool. CQC enables individuals who may wish to complain or give feedback on the quality of their care in a variety of ways. In line with the commitment CQC made in the 'People and Communities' theme of its new strategy, CQC is improving how it encourages and enables people to share their experiences. This work has focused on making it easier for people to share information with CQC in the first place, improving how CQC values and uses that information, and being more transparent in reporting back to people about how CQC acts on what patients share with them.
The time bar on GMC investigations should not be a barrier to establishing a pattern of poor practice by any one clinician.	**Accept.** The GMC cannot currently consider fitness to practise concerns which are more than 5 years old (the 5-year rule). The 5-year rule was highlighted by both the Paterson Inquiry and the Report of the IMMDS Review as a potential barrier to public protection. **Next steps**: DHSC is currently modernising the legislation that governs professional regulators. On 24 March 2021, the Department published the consultation document, 'Regulating Healthcare Professionals, Protecting the Public'. This document consults on the Department's proposals for reform, including the proposal to remove the 5-year rule, allowing regulators greater discretion to consider whether a concern should be considered.
The bodies that have received complaints about the interventions under review should reassess what they have been told and	**Accept in principle.** **System-wide action**: In 2018, 8 health and social care regulators and other bodies

Action for Improvement	Government response
satisfy themselves that they have taken necessary steps to identify any patterns and trends. They should inform the relevant organisations and Patient Safety Commissioner of outcomes of concern	launched the Emerging Concerns Protocol, a new agreement to help them share concerns with each other more effectively. **GMC:** The GMC has, since 2006, completed 18 investigations into complaints relating to mesh (including Hernia Mesh), 5 investigations into complaints relating to Sodium Valproate and no investigations into complaints relating to Primodos. The GMC are also undertaking further work to improve information sharing between regulatory bodies and to promote joint analysis of emerging risk. Key priorities are: reviewing how low-level concerns which may not meet the threshold for investigation are shared; developing a shared understanding of factors that characterise high or low performance service providers; and developing a shared data platform with the Nursing and Midwifery Council. **CQC**: From an initial review of past complaints, the CQC are satisfied that they are taking the necessary steps to identify any patterns of concern or trends but will undertake further sampling of other sources of information they hold. **Parliamentary and Health Service Ombudsman (PHSO):** the PHSO reviewed complaints that were in scope of the Review, and shared learning from these with the Review team in July 2019. They were unable to comment on the use of Primodos as this pre-dated PHSO's NHS jurisdiction. They undertook a sampling of 125 maternity cases but found none referred to the use of sodium valproate. They identified 2 cases that we had investigated about surgical mesh and had been partly upheld. While we did not find any clinical failing, we did see failings in the communication of the risks associated with mesh procedures. In December 2019, PHSO introduced a

Action for Improvement	Government response
	new digital system to manage casework. This has enabled the PHSO to more easily identify and understand emerging themes and trends in complaints. The PHSO shares systemic learning from casework through publications and engagement with stakeholders, to help make improvements to the quality and safety of NHS care and treatment. **Trust level:** At a Trust level, the Patient Safety Action Plan will work to improve the way the NHS handles complaints and concerns including to drive a more open and transparent culture. Specific actions include commissioning behavioural analysis to support improvement in the NHS's first response to feedback, and working with the PHSO to support their work to pilot a new set of complaints standards and complaint handling training.
Organisations who take complaints from the public should designate a non-executive member of the board to oversee the complaint handling processes and outcomes, and ensure that appropriate action is taken	**Accept in principle.** Senior leaders play an important role in creating an open and honest culture and improving the way complaints and concerns are responded to in the NHS. DHSC is developing a Patient Safety Action Plan, which will set out a specific set of actions for improving the way the NHS responds to complaints and concerns.

3. Redress

3.1 **Recommendation 3 of the Report states:** *'A new independent Redress Agency for those harmed by medicines and medical devices should be created based on models operating effectively in other countries. The Redress Agency will administer decisions using a non-adversarial process with determinations based on avoidable harm looking at systemic failings, rather than blaming individuals'.*

Government response: We do not accept this recommendation. 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 provider redress where this is considered necessary, the government therefore has no plans to establish an independent redress agency.

3.2 We said in the Written Ministerial Statement of 11 January 2021 that the government has no current plans to establish a redress agency as set out in recommendation 3. 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 (for example, the ex-gratia support through the Infected Blood Support Scheme). If, as the recommendation proposes, existing redress schemes were relocated behind a single front door of a new agency, we do not see that would necessarily improve patient's redress experience.

3.3 Nor do we believe a redress agency in this country would necessarily make products safer or drive the right incentives for industry because many decisions by pharmaceutical and devices companies are made at a global level. Our primary focus as described throughout the government's response is on improving medicines and medical devices safety, setting high standards for industry to market and manufacture products, with the aim of reducing harm in the future. The UK has one of the safest medicines systems in the world and we will continue to make sure patients and the public have access to the best and most innovative medicines.

3.4 **Recommendation 4 of the Report states:** *'Separate schemes should be set up for each intervention – HPTs, valproate and pelvic mesh – to meet the cost of providing additional care and support to those who have experienced avoidable harm and are eligible to claim'*

Government Response: 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.

3.5 The Report calls for redress schemes to be set up for each intervention, separate to the agency recommended under recommendation 3. For HPTs this is ‘in view of the stress, anxiety, psychological harm, and toll of fighting for recognition’. For Sodium Valproate and Mesh, this is to meet the cost of providing additional care and support to those who have experienced avoidable harm and are eligible to claim.

3.6 Patients have the right to take healthcare providers to court for clinical negligence, or manufacturers to court for product liability. We appreciate many patients that the Review team have spoken to have not been successful in achieving redress through these legal routes, although for valproate and pelvic mesh, claims have been successful for some but not other patients. The report calls for redress for each intervention in the form of 'ex gratia' schemes. These are voluntary payments made by governments or others to harmed groups where there is no legal liability to do so.

3.7 We discussed recommendations 3 and 4 with the Patient Reference Group, including informing the Group in advance that the government had said in the WMS of 11 January that we have no plans to establish an independent redress agency. Group members shared views on a number of issues. This included feedback on the effectiveness of seeking redress through existing routes including litigation, and views on recommendations 3 and 4.

3.8 While the government is sympathetic to the experiences of those patients who gave evidence to the report, our primary focus is on improving future medicines and medical devices safety. It is therefore crucial that we focus government funds on initiatives that directly improve future safety (including specialist mesh centres and support for families affected by medicines in pregnancy). For this reason, redress schemes will not be established in response to recommendation 4.

Actions for improvement

Redress

3.9 The Report contains one Action for Improvement related to redress, set out below:

Action for Improvement	Government response
There is a need for additional training for those carrying out assessments for DWP based on the insight condition reports. This should help those carrying out the assessments to make equitable decisions.	**Accept in full for sodium valproate and vaginal mesh**. Pause on Hormonal pregnancy tests due to live litigation. Entitlement to Personal Independence Payment (PIP) is assessed on a person's ability to undertake certain everyday tasks rather than the health condition/disability itself. PIP was developed with independent health, social care and disability experts, including those with experience of the benefit system. Guidance on a range of disabilities (condition insight reports) is one of the resources assessors can use when making PIP decisions. Condition insight reports on mesh and sodium valproate have been completed and may be used by assessors when preparing to make an assessment to better understand a claimant's condition, any sensitivities they should be aware of and how to best evaluate the claimant against the criteria. Condition insight reports are often developed with input from stakeholder groups that advocate for those with the relevant condition. Assessment providers have regular engagement with organisations representing disabled people discussing PIP, including the PIP assessor's training. Assessors must conform to a rigorous set of quality standards and training. Guidance on the third area of concern (hormone pregnancy tests) is paused in view of current litigation. The absence of this internal guidance does not prevent people from applying for health and disability benefits: there has been no change to the ability of an individual who believes they have been affected by a hormone pregnancy test to potentially access welfare support. **Next steps:** Everyone will have an opportunity to respond to the Health and Disability Support Green Paper. The Green

Action for Improvement	Government response
	Paper will explore how the welfare system can better meet the needs of disabled people and those with health conditions now and in the future.

4. Pelvic mesh

4.1 **Recommendation 5 of the Report states:** *'networks of specialist centres should be set up to provide comprehensive treatment, care and advice for those affected by implanted mesh; and separately for those adversely affected by medications taken during pregnancy'*.

4.2 This chapter updates on the work of the first part of the recommendation – specialist mesh services, as well as wider work on pelvic mesh. The second part of the recommendation relating to medicines taken during pregnancy, is addressed in chapter 5..

Specialist mesh services

Government response: We accept this recommendation. NHS England and Improvement has led work to establish specialist mesh services. There are now 8 specialist centres in operation. Further work is being taken forward to enhance data collection to report every pelvic floor and comparative procedure to a central database.

4.3 The establishment of specialised centres was recommended by the NHSEI Mesh Oversight Group Report in 2017. It recommended that a national specialised commissioning team were to develop, consult on and approve a service specification for centres to provide an experienced team for mesh removal. This team would include advice on referral and multi-disciplinary assessment to consider mesh removal, and surgery by expert teams. In addition, a limited number of provider centres were recommended to be selected to strike a balance between geographical access and maximising centre activity to rapidly build expertise. These centres were to be linked by a national network to report treatment outcomes.

4.4 The NHSEI Specialised Women's services clinical reference group (CRG) have since led the development of *'Specialised services for women with complications of mesh inserted for urinary incontinence and vaginal prolapse (16 years and above)'*.

4.5 Recommendation 5 of the Report re-enforced the need for the commissioned Mesh Centres to network across providers to ensure each service provides comprehensive treatment, care and advice services for those affected by implanted mesh. The NHSEI specialised commissioning team worked with the 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 patient stakeholders in September 2020 and it was concluded that no changes to the service specification were required.

4.6 The service specification, which was outlined in the procurement process, includes working across providers and with commissioners to develop best practice and to streamline the national approach. This includes providing detailed protocols and pathways, patient information and standard patient consent mechanisms. The full service specification can be found on the NHSEI website.

4.7 An invitation to tender was advertised in September 2019 for the delivery of specialised services for women with complications of mesh inserted for urinary incontinence and vaginal prolapse. It closed in October 2019 and eleven bids were received and assessed.

4.8 Following this assessment, NHSEI commissioned the following Trusts to provide specialised services for women with complications of mesh:

- Newcastle Upon Hospitals NHS FT
- Sheffield Teaching Hospitals NHS FT
- Manchester University NHS FT
- Cambridge University Hospital NHS FT
- University College London Hospitals NHS FT
- University Hospitals of Leicester NHS Trust
- Nottingham University Hospitals NHS Trust
- University Hospital Southampton NHS FT

4.9 The specialised services became operational on 1 April 2021 and mobilisation plans were developed to enable patients to be treated by these services. For some women, this may involve a transfer of care and treatment from their current NHS hospital to the specialised service. The specialised mesh services will aim to see patients as quickly as possible while managing the impact of COVID-19 on waiting times for services, and will ensure that patients can be seen safely. It is important that women have choice over their surgeon where possible, and when patients request treatment for mesh complications, they can exercise patient choice and be referred to another centre if they wish.

4.10 This service specification covers the multi-disciplinary team management, including surgery for women with mesh complications consequent to mesh

insertion vaginally or abdominally for urinary incontinence and prolapse. All women with mesh complications must be treated by a Mesh Service's Multi-Disciplinary Team (Mesh MDT).

4.11 The Mesh MDT includes the following membership:

Core members	Other membership (optional)
• named consultant sub-specialist in urogynaecology • named consultant Urologist with expertise in female urological conditions • consultant Radiologist with expertise in pelvic floor imaging • a specialist in pain management with an expertise in pelvic pain • a specialist nurse (urogynaecology, urology or incontinence)	• named colorectal Surgeon with expertise in pelvic floor problems • a pelvic floor specialist physiotherapist • a plastic surgeon • a neurologist • a psychologist • a psychosexual counsellor • an occupational therapist • access to a member of the Care of the Elderly team • a gastroenterologist • other specialist imaging • a neurosurgeon

4.12 All surgeons providing complex surgery for urinary incontinence and vaginal and uterine prolapse must be members of the appropriate subspecialist society, and all urogynaecologists must have British Society of Urogynaecology (BSUG) membership. Finally, all urologists forming part of the specialist MDT must have membership of Female, Neurological and Urodynamic Urology section of the British Association of Urological Surgeons.

4.13 Mesh Services must provide patients with information on all mesh and non-mesh treatment options, types of treatment and risks, and allow patients time to consider their options and obtain patient informed consent for treatment. To support this

process, NHSEI and NICE have developed patient decision aids (PDAs) in co-production with patient representatives, as well as seeking comments from a very wide range of stakeholders. NHSEI will be evaluating the PDAs in practice during 2021/22.

4.14 Prior to any surgery, shared decision-making between clinicians and patients must include whether a full or partial removal is planned, and the potential risks if it becomes clear during the procedure that a full removal is not safe, nor possible. Even when a full removal is planned, this may not always be feasible due to complications revealed during the operation, so all the potential outcomes must be discussed in advance.

4.15 An update was presented to the Patient Reference Group on progress to establish and operationalise the specialised mesh services. The Group provided useful feedback on a number of areas, including the importance of the right data being collected, with a focus on the need for enhanced patient reported outcome measures. The Group also discussed the importance of patients being given the necessary information and patient decision aids, and the importance of the specialised services working together and sharing data on patient outcomes.

Next steps:

4.16 NHSEI will work to ensure that there will be a continued transfer of patients to the specialised services.

4.17 There is currently no specialised service within the South West NHS region. Good progress is being made towards the establishment of a regional service with a South West provider. NHSEI will announce the location of the South West provider in due course.

4.18 All specialised services for women with complications of mesh must meet annually at a Clinical Summit to present data and discuss outcomes. The annual Clinical Summit will include discussion of clinical performance and outcomes, including surgical and non-surgical outcomes and patient feedback.

Enhanced data collection - the Pelvic Floor Information System

4.19 Recognising the need for enhanced data collection, as part of the announcement of the Review in February 2018, the then Secretary of State Jeremy Hunt announced the provision of £1.1m to develop a comprehensive database of urogynaecological procedures, including vaginal mesh, to treat pelvic organ

prolapse and stress urinary incontinence, improve clinical practice and identify issues. The establishment of such a database was also a recommendation of the Mesh Oversight Group report of 2017. In December 2019 the Secretary of State issued a Direction to NHS Digital (updated in July 2020) to enable NHS Digital to establish and operate the database, now known as the 'pelvic floor information system'.

4.20 The information system has started to receive live data, including historical data from July 2017 onwards, with an initial focus on supporting pelvic organ prolapse (POP)/ stress urinary incontinence (SUI) and removal centre organisations to report every pelvic floor and comparative procedure to this national database. The reporting of every procedure is one of the conditions of the 'pause' on mesh (see paras 4.25-4.27).

Next steps

4.21 The Report recommends that the development of the information system *'should be combined with a selective retrospective audit of a defined cohort of women who have undergone mesh procedures some years ago, in order to establish the rates of complications in the long term'*. The government accepts this recommendation, and DHSC has commissioned NHS Digital to scope and deliver this retrospective audit with the findings of this audit published upon completion.

4.22 The establishment of a clinical registry function to sit alongside the pelvic floor information system was recommended by the Report. This would bring together patients, clinicians, data scientists and analysts to complete detailed analysis and drive insight from urogynaecology data to support surveillance and identification of follow-ups by clinical bodies, regulators and commissioners to act on. A clinical registry function for pelvic floor & urogynaecology will be considered as part of work on the Medical Device Safety Programme.

4.23 The Report also notes the need for a validated patient reported outcome measure (PROM) or patient reported experience measure (PREM) related to mesh, and recommends that one is developed. The government accepts this recommendation. Development, testing, evaluation and validation of a new PROM can take 2-3 years and requires patient, clinical and specialist academic input to ensure the data collected is suitable for outcome-based analysis and evaluation. The government has accepted the recommendation in the Report for a validated PROM. A new validated PROM for pelvic mesh procedures is expected be commissioned through the National Institute of Health Research in 2022, subject to receiving high quality bids. The funding call is being aligned with the findings from the qualitative research on experiences of urogynaecology services, which was commissioned earlier this year. Preliminary findings and outputs of this study

will be available in April 2022. Recognising patients' calls for a wider range of outcomes to be recorded, DHSC has also commissioned NHS Digital to work with patient groups and clinicians to develop a patient questionnaire. This will be used alongside existing PROMs in the interim until the new validated PROM for pelvic floor is developed.

4.24 The work to establish the Pelvic Floor Information System and related work including the patient questionnaire and PROM development, will also provide valuable insights to inform the scoping and design of the Medical Devices Information System (MDIS) - see chapter 8.

The High Vigilance Restriction on the use of mesh

4.25 In July 2018, and in response to concerns raised by the Review Team, the government announced that a High Vigilance Restriction, informally referred to as a 'pause', in the use of vaginally inserted mesh to treat prolapse and the use of tape or slings to treat SUI should be instituted immediately. This was to be done through implementation of a high vigilance programme of restricted practice to allow the NHS to put in place a consistent, high-quality service that adequately meets the conditions set out by NHSEI. Thereby, the NHS issued a ‘High Vigilance Restriction’ and national pause in the use of surgical mesh/tape to treat SUI for urogynaecological prolapse.

4.26 Both the Chief Medical Officer and Baroness Cumberlege recommended that a blanket ban of the relevant procedures should not be introduced, and that there is need to have some exceptions within the high vigilance programme of restricted practice. The restriction period was formally extended in March 2019 and is still in place.

Next steps:

4.27 The High Vigilance Restriction will remain in place until the conditions are met, including the development and implementation of specialised mesh centres for women with complications of mesh inserted for SUI/POP. NHSEI are monitoring progress on meeting the conditions of the national pause on vaginal mesh insertion procedure and changes will only be made following consultation with stakeholders including patients, professional bodies and other NHS organisations.

Strategic leadership - the 'Pelvic Floor Health Oversight Group'

4.28 To improve care for women with pelvic floor health issues nationally, NHSEI established a ‘Pelvic Floor Health Oversight Group’ in August 2019. It continues the work of previously established stakeholder groups, including the Mesh Oversight Group, which were responsible for setting and communicating the conditions of the national pause on vaginal mesh insertion procedures to the NHS and private providers in July 2018. The Pelvic Floor Oversight Group has been considering the pelvic mesh related recommendations and Actions for Improvement from the report as part of a broader programme of work (for more detail on progress on the Actions for Improvement please refer to the table at the end of this chapter).

4.29 The Oversight Group benefits from patient and clinical expertise, as do its various work streams which are currently working on:

- improving the prevention and identification of pelvic floor dysfunction and improving access to specialist care perinatally
- establishing the enhanced data collection for the pelvic floor information system and a clinical registry (as described above)
- the development and implementation of specialist mesh services for women considering mesh removal (as described above)

Next steps:

4.30 NHSEI is establishing two further subgroups to develop better pathways for women experiencing stress-urinary incontinence (SUI) and pelvic organ prolapse (POP), and further opportunities to develop research and promote education and training in pelvic floor health.

Actions for Improvement

Pelvic mesh

4.31 The Report contains 15 Actions for Improvement related to pelvic mesh, set out below:

Action for Improvement	Government response
Further research is urgently needed so that a clearer view can be reached on the inherent properties and safety of pelvic mesh.	**Accept in principle.** The National Institute for Health Research (NIHR) welcomes funding applications for research into any aspect of human health, including the safety of pelvic mesh; it is not usual practice to ring-fence funds for particular topics or conditions. **Next steps:** Applications are subject to peer review and judged in open competition, with awards being made on the basis of the importance of the topic to patients and health and care services, value for money and scientific quality. The NIHR has commissioned a half-million-pound 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).
Medical device manufacturers must research and develop a remedial strategy to address any severe complications caused by their product. This strategy should be set out in the Instructions for Use (IFUs) and guidance. The strategy should be developed collaboratively with appropriate input from others, such as the regulators and the commissioners of any services required to carry out actions.	**Accept in principle.** The government is determined to strengthen the current UK regulatory regime for medical devices to increase patient safety, enhance regulatory transparency, increase medical device traceability and drive additional pre-market scrutiny of medical devices. A controlled introduction and proactive clinical follow up provides the opportunity for the early identification of unexpected safety issues and remedial actions. Manufacturers publishing a remedial safety strategy would need to illustrate how their device is expected to perform, discrepancies in performance, an analysis of the reasons and plans to address the gap between anticipated and actual performance. This would provide reassurance to patients. Plans could only be based on anticipated harms, and remedial strategies to address unanticipated harms may be subject to change.

Action for Improvement	Government response
	Next Steps: The MHRA is developing plans to ensure the UK has a world-leading regime that draws on international best practice. The government plans to formally consult on the proposed future regime for medical devices through a formal public consultation later this year. This will include consideration of this action for improvement.
We recommend that when a device or procedure is introduced a cohort of early recipients undergo enhanced reporting to detect unexpected adverse impacts.	**Accept in principle.** The government is determined to strengthen the current UK regulatory regime for medical devices to increase patient safety, enhance regulatory transparency, increase medical device traceability and drive additional pre-market scrutiny of medical. **Next steps:** A controlled introduction and proactive clinical follow up provides the opportunity for the early identification of unexpected safety issues and remedial actions. Manufacturers publishing a remedial safety strategy would need to illustrate how their device is expected to perform, discrepancies in performance, an analysis of the reasons and plans to address the gap between anticipated and actual performance. This would provide reassurance to patients. Plans could only be based on anticipated harms, and remedial strategies to address unanticipated harms may be subject to change.
NICE's most recent guidance states that the Transvaginal Tension Free Vaginal Tape-Obturator (TVT-O) should not be offered routinely. In the future, we feel the TVT-O should only be used in exceptional circumstances, if at all.	**Accept.** The Clinical Guidelines team consulted with the NICE Topic Adviser for Urinary Incontinence for the Clinical Guideline. The Topic Advisor has advised that NICE's guidance with respect to TVT-O mirrors that suggested by the Review, though worded slightly differently. At present, NICE recommends: "Do not offer a transobturator approach unless there are specific clinical

Action for Improvement	Government response
	circumstances (for example, previous pelvic procedures) in which the retropubic approach should be avoided." Currently, NICE does not make a specific recommendation on the relative risks and benefits of full and partial mesh removal, or which techniques and approaches should be offered. **Next Steps:** To address these points raised, NICE has undertaken an exceptional review of NG123: urinary incontinence and pelvic organ prolapse in women: management. This review did not identify any new evidence which would justify an update to the current guidance. NICE will actively monitor the situation and update its guidance as required in the event that relevant new evidence is published.
Professional bodies should lead on ensuring surgeons only operate within their capabilities. They must provide guidance for their members and ensure that surgeons are appropriately trained, and this should be assured through the appraisal process.	**Accept.** In November 2019, the British Society of Urogynaecologist set up a mentorship scheme, approved by the Specialty Education Advisory Committee (SEAC) of the Royal College of Obstetricians and Gynaecologists (RCOG). It ensured that any consultant clinician undertaking a Stress Urinary Incontinence procedure had adequate training to complete this. Currently, 26 clinicians have completed the mentorship scheme. To ensure that only those clinicians who should be performing these procedures are doing so, individuals are only able to take part in the training if a medical or clinical Director agrees it sits within the remit of the clinician’s job. This safeguard professional bodies only train those clinicians who undertake pelvic floor surgery as part of their routine practice. **Next Steps:** In Urology, although operative treatment of stress urinary incontinence is confined to consultants with a special interest in functional and reconstructive

Action for Improvement	Government response
	urology, all trainees are required to demonstrate level 4 competency regarding the management of patients with stress incontinence, as included in the advanced curriculum in Urology. Those with a specialist interest, a level 3 competency requirement ensures new consultants are appropriately trained in this subspecialty. The British Association of Urological Surgeons (BAUS) provides data pertaining to consultant outcomes, up to 2020 on their website. Going forward the Pelvic Floor Registry set up by NHS digital will be expected to capture this data. Data regarding surgical outcomes are a key part of the appraisal process and summaries have been used routinely by members for this purpose.
A culture must exist where all multi-disciplinary team (MDT) members feel able to speak up and that their input will be listened to. Trusts must work to create a culture that facilitates effective MDTs.	**Accept.** The service specification for the mesh specialist centres describes the importance of a multi-disciplinary team (MDT) approach to support treatment planning. All women with mesh complications must be discussed at the Mesh Service's MDT. Please refer to paragraph 4.11, 4.12 and 4.13 for further detail on the exact clinical membership of MDTs. **Next steps:** NHSEI is working with the mesh centres to develop a standardised approach to MDT working which includes the full range of specialised clinicians listed in the MDT. The MDT can only function if all members play an active part and all members contribute towards treatment planning. We will explore how CQC can assure itself that all hospital providers are complying effectively with up-to-date national guidance on MDT meetings in the government's response to the Paterson Inquiry.

Action for Improvement	Government response
Conservative measures must be offered to women before surgery. We have heard that specialist pelvic floor physiotherapy cannot match the current demand. The service commissioner should identify gaps in the workforce and notify specialist clinicians, professional organisations and Royal Colleges. A co-ordinated strategy can then be developed to remedy the gap.	**Accept.** The NHS Long-Term Plan commits to improving access to postnatal physiotherapy, and for all women to have access to multidisciplinary pelvic health care across England by March 2024. This will be delivered locally through the establishment of Perinatal Pelvic Health Services (PPHS). One key action for PPHS will be to recruit additional specialist physiotherapists and midwives locally and provide additional training to maternity staff to improve the prevention, identification and treatment of pelvic floor dysfunction in the perinatal period. Individuals face variation in the availability of commissioned services and care pathways. As part of the Long-Term Plan, NHSEI has committed to improving access to postnatal physiotherapy by 23/24 and ensuring that all women have access to multidisciplinary pelvic health clinics and pathways across England by referral. This commitment sits within a broader ambition to reduce the number of women living with dysfunction in England, and the associated personal, societal and financial costs. **Next Steps:** National funding will be available from 20/21 to support delivery of the Long-Term Plan commitment and wider ambition. The amount will be phased year-on-year, with limited funding to support the roll out of these clinics in some sites from 2020/21, rising to full funding for all health systems in England by 2023/24. In April 2021, 14 Early Implementer Systems (EIS) were launched to test and develop improved pelvic health support perinatally, including timely access to physiotherapy. An implementation group will observe progress and share learnings from EIS, to assist with the national roll out.
Clinicians must ensure patients have	**Accept.** NHSEI is working with patients

Action for Improvement	Government response
sufficient understanding of their treatment including the benefits, the potential risks it presents, and the alternative treatment options, including doing nothing, in order to decide whether they are willing to have that treatment.	and clinicians to identify where areas of the clinical pathways for stress urinary incontinence and pelvic organ prolapse can be improved, so that patients receive safer and more personalised care based on shared decision making and fully informed consent to procedures. As part of this, NHSEI is taking into account existing initiatives and guidance, such as the recently updated GMC guidance on Decision Making and Consent (November 2020), Patient Decision Aids produced by NICE, and Personalised and Care Support Planning to design a best practice pathway of care for stress urinary incontinence and pelvic organ prolapse. An initial scoping session has been held to identify areas for improvement as well as existing initiatives that may help to improve the care that patients receive. Design work of the pathway is at an early stage. **Next Steps:** NHSEI will work with patients, clinicians and other stakeholders throughout 2021/22 to fully develop the pathway and consider a mechanism for implementation.
Clinicians need to establish and agree terminology and definitions related to both mesh insertions and removals.	**Accept.** Patient Decision Aids have been published by NICE which clearly define terminology and definitions related to both mesh insertion and removal surgery. Details of surgery are provided in Patient Information Leaflets published jointly by BSUG and BAUS. NICE, BSUG and BAUS have worked together, and with patients to ensure all terminology used is consistent and understandable to help support the clarity of discussions with patients. The published NICE Patient Decision Aids include the following: • surgery for stress urinary incontinence: patient decision aid and user guide

Action for Improvement	Government response
	• surgery for uterine prolapse: patient decision aid and user guide • surgery for vaginal vault prolapse: patient decision aid and user guide • treating complications from mesh used for pelvic organ prolapse – Options for women referred to specialist centres: patient decision aid • treating complications from mesh used for stress urinary incontinence – options for women referred to specialist centres: patient decision aid The published BSUG/ BAUS Patient Information Leaflets on mesh removal include the following: • patient Information Leaflet for removal of tension-free vaginal tape • patient Information Leaflet for removal of transobturator tape **Next Steps:** BSUG are also working on 2 further PILs for removal of vaginal and abdominal mesh for prolapse in collaboration with BAUS and the PFS which will be published by Autumn 2021.
An audit to establish complication rates should be attempted using the women who had mesh insertions in 2010.	**Accept.** DHSC has commissioned NHS Digital to scope and deliver this retrospective audit with the findings of this audit published upon completion.
A consensus needs to be reached on whether it is better to carry out full or partial	**Accept.** The Urinary Incontinence Topic Advisor for the Clinical Guideline has

Action for Improvement	Government response
removals. This is a clinical matter, and it must be done collaboratively, including consulting international experts. This consensus should be validated by carrying out follow up on those who have removals at the specialist centres. We strongly recommend that NICE actively monitor the situation and update their guidance promptly once a consensus has been reached.	advised that NICE's guidance with respect to TVT-O is the same as that suggested by the Review, though worded slightly differently. Currently, NICE does not make a specific recommendation on the relative risks and benefits of full and partial mesh removal, or which techniques and approaches should be offered. To address these points raised, NICE has undertaken an exceptional review of NG123: urinary incontinence and pelvic organ prolapse in women: management. This review did not identify any new evidence which would justify an update to the current guidance. **Next Steps:** NICE will actively monitor the situation and update its guidance as required in the event that relevant new evidence is published. When considering more specifically the service specification for specialised services who provide treatment for women with complications of mesh inserted for urinary incontinence and vaginal prolapse, it does not distinguish between partial and full removal. Shared decision-making between clinicians and patients prior to surgery, must include whether a full or partial removal is planned, and the potential risks if it becomes clear during the procedure that a full removal is not safe or possible. Even when a full removal is planned, this may not always be feasible due to complications revealed during the operation. Therefore, all potential outcomes must be discussed in advance.
Consideration should be given to credentialing a small number of centres and surgeons for particular complex pelvic mesh surgeries.	**Accept.** GMC are currently piloting 5 early adopter credentials and hope to complete this work later this year. These are in the areas of liaison psychiatry, mechanical thrombectomy, pain medicine, rural and

Action for Improvement	Government response
	remote medicine, and cosmetic surgery. This is a learning phase to help the GMC strengthen their framework and create processes that will facilitate the development of future credentials to support patient safety. **Next Steps:** Stakeholders and patient groups have already made a strong case for a credential in mesh removal, which the GMC will assess as they move to the next phase. The GMC Curricula Oversight Group (COG) will start to prioritise areas for credentials later this year, so that submissions can be considered for approval as soon as possible once the early adopter phase is completed. When these areas have been agreed, the GMC will work with credential developers to establish a timeframe and support progress towards approval. Credentialing is also being considered by the British Association of Urological Surgeons (BAUS), the British Society of Urogynaecologist (BSUG) and the Royal College of Obstetricians and Gynaecologists (RCOG) and when in place will be linked to the centres commissioned to deliver specialised services for women with complications of mesh inserted for stress urinary incontinence and vaginal prolapse.
A remote counselling service along the lines we set up during this Review should continue to exist.	**Do not accept.** The NHSEI specification for specialised services for women with complications of mesh surgery does not include a remote counselling service. The service specification for specialised mesh centres describes how all women with mesh complications should be referred to a specialised service for women with complications of mesh. This referral will enable all women to receive a comprehensive assessment, discussions about treatment options and any further support required. Within that context, the mesh services have

Action for Improvement	Government response
	access to a range of Mesh MDT members to provide patient support, including psychologists and psychosexual counsellors.
Pelvic floor education should be encouraged, where appropriate, in schools and certainly in antenatal classes. In addition, we recommend that the NHS adopts the French model for universal post-natal pelvic floor rehabilitation.	**Accept in principle.** NHSEI has committed to improving the prevention, identification and treatment of pelvic floor dysfunction through the establishment of Perinatal Pelvic Health Services. As part of the service model being implemented and tested by 14 Early Implementer Systems, PPHS will embed education on pelvic floor health in antenatal care for all women, including how to perform pelvic floor muscular exercises as a preventative measure. PPHS will also have responsibility for ensuring that pelvic floor health is followed up in all postnatal appointments, and simplifying and improving access to NICE-recommended specialist support when women experience problems. PPHS will therefore be able to provide a more personalized approach to pelvic health care, that is proportionate to level of individual need and that takes advantage of all the local professionals in contact with women before and following birth. Furthermore, the introduction of compulsory education about relationships, sex and health in schools marks an important milestone by increasing knowledge of female sexual health, and pupils are now taught the facts about a number of areas of women's health, including menstruation, contraception, fertility, pregnancy and about the menopause. Teaching pupils about physical health and mental wellbeing will give female students the information they need to make good decisions about their own health and wellbeing. It empowers students to

Action for Improvement	Government response
	recognise issues in themselves and others and, when issues arise, they will have the confidence to seek support as early as possible from appropriate sources.
Dismissive, defensive attitudes by surgeons are a cultural issue that needs to be addressed by the medical profession, its professional bodies and regulators.	**Accept.** GMC have commenced their review of Good Medical Practice (GMP). GMP is the core ethical guidance for the medical profession and defines the professional values, knowledge, skills and behaviours required of all doctors working in the UK. Professional behaviours and culture will be a key theme of their engagement with registrants and patients. When considering mesh specifically, the British Association of Urological Surgeons (BAUS) have included extensive coverage of mesh issues for over 4 years at their annual conference pertaining to this topic. Included on the website is widespread information regarding the surgical treatment of stress incontinence and an archive of statements made by the BAUS mesh lead across this period. This degree of emphasis placed by BAUS is to ensure that women presenting with possible mesh complications are not dismissed and receive the help that they need. **Next Steps:** GMC education outcomes are also clear on the expected professional behaviours for doctors. The GMC is due to complete a review of all postgraduate curricula this year, which will require all postgraduate curricula to fully reflect the professional behaviours that are included in the Generic Professional Capabilities framework, in particular those outlined under professional values and behaviours. The GMC has approved all the surgical specialties' new curricula, and they will be going live this year. The British Society of Urogynecologists (BSUG) have included as a key component comprehensive coaching and workshops on consent in both of the main courses run by BSUG, namely the Annual Scientific

Action for Improvement	Government response
	Update and the Surgical Masterclass. They have had dedicated sessions allocated to the identification, management and service provisions for mesh complications over the past 4 years at each of their educational meetings.

5. Specialist services for those adversely affected by medicines in pregnancy

5.1 **The second part of Recommendation 5 of the Report states:** *'networks of specialist centres should be set up for those adversely affected by medications taken during pregnancy'*

5.2 This section sets out the government response to the second part of this recommendation, specialised centres for those adversely affected by medicines. The first part of recommendation 5 is addressed in chapter 4 on pelvic mesh.

Specialist services

Government response: We do not accept this recommendation. However, we recognise the underlying issue that there is a need to improve the care and support for the individuals and families affected by a range of medicines used in pregnancy, including valproate exposure. Our view is that a network of new specialist centres is not the most effective way forward. We will in instead take forward work to improve the care pathways for children and families affected by medicines in pregnancy. Additionally, we will continue work to improve the safety of medicines in pregnancy more widely, and to ensure that valproate is only prescribed where clinically appropriate. See chapter 6 for action being taken forward on sodium valproate.

5.3 We interpret the background to this recommendation as relating both to the range of conditions that may arise from use of medicines in pregnancy, with a particular emphasis on sodium valproate (valproate). The Report states that there is a need to improve the care and support for the individuals and families affected by valproate exposure during pregnancy, including access to diagnostic services and other service provision. In response, the Report recommends the establishment of specialist centres for those adversely affected by any medicine taken in pregnancy.

5.4 We recognise that there is variation in access to services across NHS regions that support children and families affected by exposure to potentially teratogenic medicines or non-prescription drugs during foetal development, for example, maternal anticonvulsants, antidepressants, non-prescription drugs or alcohol.

5.5 However, the establishment of a new network of specialist centres specifically focused on those affected by medicines in pregnancy is not viewed as the most

effective way forward. A limited number of specialist centres would not be able to provide the whole range of services that patients need for example coordinating provision across local health, education and social care systems. It is important that patients who need ongoing care can access services as conveniently as possible, and many of these services are better delivered at a local level.

5.6 Furthermore, existing specialised centres with the essential specialist expertise focus on supporting all children with neurodevelopment disorders, regardless of causation. Establishing separate centres focussed only on those affected by medicines in pregnancy could dilute clinical expertise and potentially result in a reduced service for all the patient groups involved.

5.7 Children affected by teratogenics are at risk of developing a variety of physical and behavioural problems, dependent on the specific agent of exposure. The highest prevalence observed is of cognitive, neuro-developmental, for example, communication and movement, and neuro-behavioural, for example, attention, concentration and hyperactivity disorders. There is also increased risk of other neurological challenges such as neural tube defects and epilepsy together with other organ involvement such as cardiac, kidney, orthopaedic or ear, nose and throat (ENT) impairment.

5.8 Currently, services for children with all neurodevelopmental disorders - not just those related to medicines - are primarily managed by multidisciplinary teams within Child Development Centres, which are commissioned by Clinical Commissioning Groups (CCGs). Many of the necessary aspects of assessment, support and treatment are best managed at this level to ensure joined up local services across health, education and social care systems.

5.9 These local services are supported by regional clinical networks. The regional clinical networks work with specialised NHSEI-commissioned Neuroscience Centres, which are responsible for coordinating the pathways of care across neurodisability, neurology and neurosurgery services. The specialised Neuroscience Centres are also co-located with other specialist paediatric teams.

5.10 The pathways of care for children with all neurodevelopmental disorders involve medical teams from different specialities, including obstetrics and neonatology, as well as several areas of neurosciences, at a local and a regional level.

5.11 It is of paramount importance that there is good communication and pathways of care between services who can identify infants at risk of exposure, particularly in the first 3 months of pregnancy, and who can then provide targeted developmental services and clinical follow up.

5.12 The key to the provision of comprehensive treatment is through all the services involved working together in networks, and for there to be clear pathways of care supported by agreed guidelines and protocols. There are examples of good pathways and networks of care in place that ensure joined up obstetric, neonatal and neurodevelopment co-ordinated care in parts of the London Region, the South West and North East. However, we recognise that the pathways of care are not universal and there is variation, especially in areas that are challenged by a lack of co-location of specialist paediatric clinical and developmental services with obstetrics and neonates.

5.13 The capacity and expertise to provide local and regional enhanced developmental assessment for at risk children is in place. However, more needs to be done to identify all at risk babies and ensure that targeted surveillance and treatment interventions occur in line with agreed guidelines and protocols. For example, the pan Royal College guidance on valproate use in women and girls of childbearing years also recommends routine follow up of all children exposed to valproate in utero. Clinical network arrangements need to be strengthened to ensure compliance with guidelines and protocols across all the services involved.

5.14 There is also a need to ensure that good examples of joint working between agencies and organisations are built upon and supported by patient pathways, network approaches, treatment guidelines and protocols across all NHS Regions. NHSEI will therefore take forward work to enable locally determined pathways to be developed and put in place.

5.15 For valproate specifically, the Department of Work and Pensions (DWP) has also developed a condition insight report for valproate to help assessors to better understand a claimant's condition, any sensitivities they should be aware of regarding that condition and, in light of those considerations, how best to evaluate the claimant against the assessment criteria.

5.16 We presented an update on our work to consider this recommendation to the Patient Reference Group. The Group provided discussed the challenges some families have faced in accessing diagnosis and treatment services, and provided useful feedback on what good service provision looks like. This included more of a focus on prevention and having robust processes in place to identify those at risk, clinicians being well-educated on the potential impacts of valproate and other teratogenic medicines, and being able to access specialist care in all parts of the country.

Next steps

5.17 NHSEI will take forward work to support locally-determined pathways to be developed and put in place for those affected by exposure to potentially teratogenic medicines or non-prescription drugs during pregnancy. This will help tackle the variation in access to services across NHS regions and improve the communication between services.

5.18 On valproate specifically, we are also taking forward significant work to ensure valproate is only used where clinically appropriate, and to improve patient safety for women and girls for whom there is no alternative medicine by ensuring that a Pregnancy Prevention Programme is in place and that women receive annual reviews. Further detail is set out in chapter 6 on sodium valproate.

Improving the safety of medicines in pregnancy

5.19 In the UK, three-quarters of a million babies are born each year, and more than half of expectant mothers will need to take medicines when pregnant. We are committed to improving the evidence base, and ensuring that women have high-quality, accessible information, and are able to make informed decisions about their healthcare.

5.20 Earlier this year, the MHRA has established The Safer Medicines in Pregnancy and Breastfeeding Consortium. This is a key initiative and an important example of system collaboration, as the Consortium brings together 16 leading organisations under a common pledge to meet the information needs of women and healthcare professionals, through accessible, clear and consistent advice. The group is now delivering a long-term programme of work to improve information provision for women who are contemplating pregnancy, are pregnant, or are breastfeeding.

5.21 The MHRA has also established an Expert Working Group (EWG) on Optimising Data on Medicines used during Pregnancy. In January 2021, the EWG published recommendations on how to make better use of real-world data on medicines exposure during pregnancy and breastfeeding. This will facilitate research, improve the evidence base for decision making, and enable more individual patient-relevant information to support informed decisions. It will also allow for better measuring of the impact and effectiveness of regulatory action, for example the success of a pregnancy prevention plan for a teratogen. The MHRA is engaging with wider organisations on the delivery of these recommendations. Recent progress has been made with NICE who are currently consulting on updated antenatal care guidance that aims to ensure women are asked about all medicines used during pregnancy at the maternity booking appointment, and that data is captured.

5.22 The MHRA has also secured funding from the Bill and Melinda Gates Foundation for a 2-year project to support better evidence-based dosing for medicines used in pregnancy and in related training for obstetricians. The first stage of this project will finish in September 2021. Improving this evidence will help ensure optimal efficacy and minimal toxicity of medicines, which is vitally important for the health of mother and baby. Worldwide, data in this area remain limited, and new insights could potentially impact the health of pregnant women around the world. This will also give obstetricians further clarity on the optimal dose of a medicine, when treating pregnant patients, for whom use of a medicine is necessary.

5.23 Many of the important developments mentioned above follow from the delivery of recommendations made by the Commission on Human Medicines Expert Working Group on Hormone Pregnancy Tests. The Group's report, published in October 2017, included actions to safeguard future generations via further strengthening the systems that support the safe use of medicines in pregnancy and breastfeeding.

Next steps

5.24 The Safer Medicines in Pregnancy and Breastfeeding Consortium has an ongoing programme of work to ensure pregnant and breastfeeding women can make informed decisions about their healthcare.

5.25 The MHRA is engaging with wider organisations on the delivery of the recommendations of the Expert Working group on Optimising Data on Medicines used during Pregnancy

5.26 The MHRA will complete the first stage of the project to support better evidence-based dosing for medicines used in pregnancy and in related training for obstetricians

6. Sodium Valproate

6.1 Whilst the Report of the IMMDS Review does not contain a strategic recommendation specific to sodium valproate (valproate), it discusses valproate use in much detail and contains a number of Actions for Improvement related to valproate

6.2 We are taking forward significant work to ensure valproate is only used where clinically appropriate, and to improve patient safety for women and girls for whom there is no alternative medicine by ensuring that a Pregnancy Prevention Programme is in place and that women receive annual reviews. This chapter sets out further detail on the action being taken.

Strategic leadership – the Valproate safety implementation group

6.3 The NHSEI National Director of Patient Safety has recently established a clinically-led Valproate Safety Implementation Group (VSIG) to lead work to reduce the prescribing of valproate and better support women to make informed decisions about their healthcare.

6.4 The VSIG recommends this is achieved by stopping initiation of treatment unless there are no alternatives, and deprescribing valproate when there are alternative and safer treatments available. The VSIG has 3 workstreams considering specific aspects of valproate safety. The first is focussed on valproate deprescribing, the second is considering the provision of patient Information, and the third is concerned with the Pregnancy Prevention Programme.

Strengthening regulation and the Valproate Pregnancy Prevention Programme

6.5 The MHRA has responsibility for updating the terms of the Marketing Authorisation of valproate in line with the latest scientific evidence of safety and efficacy; for the availability of information to support safe use; and for the collection of data to support evaluation of the effectiveness of risk minimisation measures, in particular the Valproate Pregnancy Prevention Programme.

6.6 In April 2018 the MHRA implemented a strengthened regulatory position on valproate. Valproate must not be used in any woman or girl able to have children unless she has a Pregnancy Prevention Programme in place. This is designed to make sure patients are fully aware of the risks and the need to avoid becoming

pregnant. These regulatory measures, announced following an in-depth review of the risk, also include a ban on the use of valproate for migraine or bipolar disorder during pregnancy, and a ban on the use of valproate to treat epilepsy during pregnancy unless there is no other effective treatment available.

6.7 In order to keep the valproate Marketing Authorisation up to date, the MHRA has been conducting a reassessment of the use of valproate in the treatment of bipolar disorder. Clinical advice is that there are effective alternative treatment options for acute mania which are safer to use during pregnancy. With respect to epilepsy, the MHRA will consider further whether the indications for paediatric use of valproate could be better specified in the product information to ensure the initiation of girls on valproate only occurs when strictly necessary.

6.8 In terms of supporting access to information to support safe use, the MHRA is planning to consult on an amendment to the Human Medicines Regulations which would require pharmacists to supply sodium valproate in the manufacturer's original pack. This will ensure that prescriptions for valproate are dispensed with a patient information leaflet and information on risk minimisation measures.

6.9 Healthcare professionals who seek to prescribe valproate to their female patients must make sure the patient is enrolled in the Pregnancy Prevention Programme. This includes the completion of a signed risk acknowledgement form when their treatment is reviewed by a specialist, which must take place at least annually.

The Valproate Registry

6.10 In 2018 MHRA and NHS Digital began work to establish the valproate registry, to support the strengthened regulatory position. Each step of the registry planning has been informed by discussion with the MHRA's Valproate Stakeholder Network which includes patient groups and charities, health professional bodies and healthcare system organisation.

6.11 The registry contains data on all NHS prescriptions of valproate in women and girls of childbearing age in England, and the first report from the valproate registry was published on 11 February 2021. This report presents an important step to improving our ability to monitor implementation and compliance with the Pregnancy Prevention Programme. This report will help us to understand changes in the use of valproate and their impact on maternal and child health, and to facilitate further research on the safety of valproate, in particular with regard to child outcomes. The valproate registry also forms the basis on which to build the anti-epileptics registry, which was also recommended in the Report.

Next steps:

6.12 A second report from the Valproate Registry is planned for September 2021. This will include an additional 8 months of data and a number of additional analyses of the core register. The next steps for the valproate registry are the building and integration of a digitalised annual risk acknowledgement form into the registry to fully monitor adherence to the Pregnancy Prevention Programme. There are also plans to extend the registry to the whole of the UK, and to enable women themselves to add data to the registry to inform its findings.

6.13 The MHRA and NHS Digital are also working to expand the registry to other anti-epileptic drugs later this year, as recommended by the Report. The MHRA and NHS Digital are also working to develop a framework for comprehensive national Medicines in Pregnancy Registries which can give a better understanding of the use, benefits, and risks of medicines taken in pregnancy.

6.14 We will introduce statutory provisions for the establishment of publicly held medicines information systems through the recently published Health and Care Bill. Our aim is to enable the development and maintenance of centrally operated medicine registries, and to ensure that all patients prescribed a specific medicine are known to the relevant registry. This would support work to ensure that prescribing is in line with guidance, and for evidence needed to make fully informed decisions can be shared with patients and prescribers.

Identifying safer alternatives to valproate

6.15 On 7 January 2021, the MHRA published the conclusions of Antiepileptic drugs: review of safety of use during pregnancy, which was conducted by the Commission on Human Medicines. The review concluded that lamotrigine and levetiracetam are safer to use during pregnancy than other epilepsy medicines including valproate. This will facilitate the switching women to alternative antiepileptic medicines. The review's findings will help inform discussions between women with epilepsy and their clinicians at initiation of treatment, routine annual reviews, and if a woman is planning to become pregnant.

6.16 Following this safety review, a patient safety leaflet, which has been developed with input from patient organisations and patient charities, has also been made available to help support the discussions between a woman and her healthcare professionals. These regulatory measures are supported across the NHS with other authorities also making changes. NICE has updated all of its guidelines where the products in question are mentioned to include the Commission's advice.

6.17 The findings of the safety review of the safety of anti-epileptics in pregnancy also have relevance for women with bipolar disorder as some anti-epileptics are used for this. Clinical advice is that there are effective alternative treatment options for acute mania which do not carry the same teratogenic risk as valproate. In order to keep the valproate Marketing Authorisation up to date, the MHRA has been conducting a reassessment of the risks and benefits of valproate in the treatment of bipolar disorder

6.18 Chapter 7 on MHRA reform updates on wider work to improve the safety of medicines in pregnancy.

Actions for Improvement

Valproate

6.19 The Report contains 15 Actions for Improvement related to valproate, set out below:

Action for Improvement	Government response
An indicator on safe prescribing in pregnancy should be introduced for future iterations of the Quality and Outcomes Framework (QOF).	**Do not accept.** Developing indicators in this area specifically for use in QOF is complicated due to the small numbers of patients who are prescribed valproate at a practice level. NHSEI is instead considering what further action can be taken outside of QOF to support the safer prescribing of valproate. The VSIG have worked with primary care colleagues on the prescribing of valproate as a potential trigger for a Structured Medication Review (SMR) and this has been included and launched in the updated SMR guidance, published 31 March 2021. The 2021/22 Network Contract Directed Enhanced Service includes this update to requirements relating to delivery of a structured medication review (SMR) of valproate and medicines optimisation service for Primary Care Networks (PCNs). PCNs must proactively consider ensuring that SMR of valproate are undertaken when planning, implementing and delivering the

Action for Improvement	Government response
	service. The SMR triggers a practice-focused prescribing safety report that will ensuring that women and girls on valproate are made aware of the potential harm if used in pregnancy and not having annual specialist reviews. **Next steps**: NHSEI will continue to review developing new incentivised indicators for GP practices.
In our view, a clear process should be agreed to ensure women are able to get appropriate counselling related to their epilepsy treatment and contraceptive choices.	**Accept**. As part of the valproate Pregnancy Prevention Programme (PPP) all women currently on valproate should be contacted for an annual medication review. NHSEI are aware that it has not happened in all cases, as such, NHSEI have recently written directly to all women of childbearing age, outlining the risk of harm to the foetus in pregnancy and the requirement for prescribed valproate to be on highly effective contraception. The letter asks women to see their GP or specialist with a copy of the letter. The VSIG recommended the development of a national shared care protocol (SCP) for valproate as there has been some confusion among prescribers and clinicians regarding responsibilities for monitoring those who use valproate. A national SCP for valproate has been developed and prioritised in the national care protocol system which has been recently launched, and the national SCP for valproate is currently under consultation. The SCP will represent the minimum information required to allow safe, effective sharing of prescribing of valproate. Upon publication, individual organisations are expected to consider adapting these SCP templates for local adoption. The Medical Royal Colleges have also produced helpful guidance for counselling related to epilepsy treatment and

Action for Improvement	Government response
	contraceptive choices, to achieve better consistency across primary and secondary care. The VSIG contributed to GMC case studies which have been formally approved by regulators GMC, NMC, GPhC and are jointly published on the respective websites. **Next steps:** The VSIG has also created a working group to look specifically at deprescribing risks. The members of this deprescribing working group will observe the risks of deprescribing, and potential harm from sudden death in epilepsy (SUDEP), relapse and self- harm.
Information should be collected to identify those already affected by exposure to valproate in utero to ensure they have access to diagnosis and support, and to plan service provision.	**Under consideration**. NHSEI will consider the feasibility of a process to identify those exposed to valproate in utero. The valproate registry contains data dating back to 2018 so further work is needed to establish the feasibility of identifying those exposed prior to 2018, for example through prescribing data.
A prospective registry should be established for all women on anti-epileptic drugs who become pregnant, to include mandatory reporting of data relating to them and their child(ren) collated over lifetimes. This registry could potentially be expanded to collect data on paternal and transgenerational effects.	**Accept.** The first report of the valproate registry was published on 11 February 2021, and a second report from the valproate registry is planned for September 2021 **Next steps:** next steps are for the valproate registry to be expanded to cover all anti-epileptic drugs, and to enable women themselves to add data. MHRA and NHS Digital will also integrate a digital annual risk acknowledgment form to fully monitor adherence to the Pregnancy Prevention Programme. The valproate registry will also be extended to all regions in the UK.
The relevant stakeholders should continue to work with patient groups to monitor and improve the Pregnancy Prevention Programme and to consider the next steps, which should include NHS England and	**Accept.** As detailed above, NHSEI have recently written to all women and girls of childbearing age prescribed valproate in England to ask them to see their general practitioner or a specialist on an annual

Action for Improvement	Government response
NHS Improvement (NHSEI) writing directly to all women and girls of childbearing potential, asking them to see their general practitioner or specialist	basis. Additionally, NHSEI have recruited and appointed 3 patient and public voice representatives (PPV). These representatives are also members of the Valproate Safety Implementation Group. NHSEI are working with the PPV to develop a communication and engagement plan to the engage patient groups, and relevant charities in due course. **Next steps:** The VSIG has also created a PPP working group to look specifically at creating a shared protocol and improving links between neurology mental health, primary care and contraceptive providers. The members of this working group including the 3 patient and public voice representatives have been tasked with improving compliance of Annual Risk Acknowledgement Form (ARAF) at the point of dispensing and prescribing and creating a digital version of ARAF form.
Clinicians should continue to follow guidance regarding prescribing of valproate and alternatives for all indications.	**Accept.** The answer has been provided in response to the action *'In our view, a clear process should be agreed to ensure women are able to get appropriate counselling related to their epilepsy treatment and contraceptive choices' on page 51.*
A system similar to the Pregnancy Prevention Programme should be used where teratogenicity is well-known or the effects are severe. Alternatively an acknowledgement of risk form should be attached to the prescribing and/or dispensing of all medication considered to have teratogenic potential or known to have a risk above that of the general population	**Accept in principle.** The MHRA accepts the need for robust risk mitigation measures for all teratogens but the exact measures will depend on the magnitude of risk associated with the medicine in question and its intended use. The MHRA is reviewing the requirements already in place in the UK and the EU for medicines known or suspected to be teratogenic, as part of the safer medicines in pregnancy programme of work. The next step will be to consider these in the context of risk mitigation programmes of other regulators to develop a consistent improved approach to avoid inadvertent exposure of

Action for Improvement	Government response
	these medicines that takes into account levels of risk and clinical use. **Next steps:** Stakeholder input and expert advice will be sought on the feasibility and risk proportionality of the proposed measures for use in the UK. Once agreed, UK guidance will be issued and requests for amendments to risk mitigation for specific products will be requested, as appropriate. MHRA will update as this work progresses.

7. MHRA transformation to put patients first

7.1 **Recommendation 6 of the Report states:** *'the Medicines and Healthcare products Regulatory Agency (MHRA) needs substantial revision particularly in relation to adverse event reporting and medical device regulation. It needs to ensure that it engages more with patients and their outcomes. It needs to raise awareness of its public protection roles and to ensure that patients have an integral role in its work'.*

Government response: We accept this recommendation. The MHRA, reflecting its corporate Delivery Plan for 2021-2023 "Putting patients first - A new era for our Agency", has initiated a substantial programme of work to improve how it listens and responds to patients and the public, to develop a more responsive system for reporting adverse incidents, and to strengthen the evidence to support timely and robust decisions that protect patient safety. The MHRA is transforming organisational culture to ensure patient safety remains at its core.

Transforming culture

7.2 The MHRA has made addressing the Report's recommendations central to its new corporate Delivery Plan for 2021-2023 “Putting patients first - A new era for our Agency”. The Delivery Plan is a focused 2-year programme of work that aims to transform the organisation. Involving patients is the MHRA’s first priority, and the plan lists specific actions designed to address the Report's concerns.

7.3 The MHRA recognises that a change in its culture is necessary and has taken several steps to help deliver this. The MHRA has recruited a newly created Chief Safety Officer post and has established a Patient Safety and Engagement Committee, which advises and provides assurance to the Board in relation to its responsibilities regarding patient safety and engagement. This marks an important moment in the MHRA’s commitment to patient safety.

7.4 Supporting this development are a change programme and new staff values that aim to more firmly embed patient outcomes. This will ensure that the organisational culture has patient safety at its core.

7.5 Additionally, the Conflict of Interest policy for the Commission on Human Medicines (CHM) and Expert Advisory Groups has been reviewed to further

strengthen governance to ensure consistency and transparency in the decision-making process for handling potential conflicts.

Next steps

7.6 The newly-appointed Chief Safety Officer will lead the MHRA's ongoing implementation of the recommendations from the Report. This will help to ensure that the MHRA continues delivering on their commitment to keep patients safe. The post holder will oversee the development of a revitalised approach to vigilance of both medicines and medical devices. This is a key senior appointment in the strengthened MHRA leadership and governance, and it is an important example of change within the MHRA and a response to the Report.

7.7 The MHRA will launch a public consultation on a revised CHM code of practice, which will cover conflicts of interest. This is planned for summer 2021, and the MHRA aims to implement the revised code by the end of 2021.

Patient involvement

7.8 In May 2021, the MHRA published a Patient and Public Involvement Strategy for public consultation that sets out how the Agency will deliver a step change in its involvement and engagement with patients. This builds on recent progress and a previous consultation in 2019 that asked patients how they can best engage and involve them in their work.

7.9 The strategy aims to ensure the MHRA develops and introduces clear processes for engagement and involvement, to ensure teams have a systematic means of engaging and involving patients and the public in their work and that the MHRA publishes how it does that. The MHRA intends to have these processes embedded by June 2022.

7.10 Since the Report was published, patients have actively contributed to MHRA activities in workshops and committees on a wide range of topics from COVID-19 vaccination communication materials to medical device regulation.

7.11 The MHRA aims to achieve greater consistency in patient representation on decision-making committees by ensuring that there are two patient representatives for each Committee. The MHRA is also strengthening its Patient Group Consultative Forum to increase its size and to ensure that it is representative in terms of its breadth and diversity. The Forum acts as a means of bringing the patient and public voice into the MHRA and is a large pool of patient representatives who are actively involved in the MHRA's work. These patients will be provided with training and guidance to ensure that they are able to engage

meaningfully. A further improvement is the creation of an insight exchange forum so that patients can share insights within the Agency and with partners across the health sector.

7.12 The MHRA presented a progress update to the Patient Reference Group in April, covering work on the Patient and Public Involvement Strategy; developing a more responsive safety and reporting system; and improving evidence for patient safety decisions. The Group shared a number of suggestions on how adverse event reporting could be strengthened, and how the MHRA can involve patients more in everything it does. The MHRA is grateful to the Group for a useful, thought-provoking and challenging session. Members of the group rightly wanted to see further action in terms of implementation, and the MHRA offered a further meeting with the group over the summer to discuss the MHRA's Patient and Public Engagement Strategy and further aspects of the MHRA's work to strengthen our it's safety systems.

Next steps

7.13 Public consultation underway on the Public Engagement and Involvement Strategy. The MHRA plans to collate responses and publish the final strategy later this year, and to have the new processes embedded by June 2022.

7.14 The MHRA will review and improve patient representation across all decision-making committees, to ensure there is patient representation across all, with training provided. This is linked to the expansion of the Patient Group Consultative Forum.

Improving adverse event reporting

7.15 Substantial progress has been made on overhauling the UK's adverse event reporting system. New technologies have been introduced for the reporting of adverse events under the Yellow Card system for products used to treat Coronavirus as well as vaccines. In particular, the MHRA Safety Connect programme will introduce a brand new and more responsive vigilance service to detect and respond to safety concerns with any medicine, medical device or blood product more quickly and more comprehensively than ever before.

7.16 This will significantly improve how the MHRA interacts with patients and how it monitors and acts on safety issues, through joined up safety vigilance, reporting and information.

Next steps

7.17 The Safety Connect system will be fully in place by March 2022 and a number of changes have already been made, for example making it easier to report and respond to side effects of coronavirus vaccines and treatments. The MHRA has been engaging with patients and the public directly to gain user feedback and perceptions on the Safety Connect programme via user needs sessions. The feedback gathered through these sessions is being used to help ensure the requirements of the new system are met for patients and that it provides a more user-friendly service.

Strengthening the regulatory framework for medicines and medical devices

7.18 Following the United Kingdom's departure from the European medicines regulatory system, the MHRA is seizing the opportunities to evolve the United Kingdom's regulatory framework. The Medicines and Medical Devices Act 2021 (MMD Act) presents a unique opportunity to update the regulatory framework for medical devices, medicines and clinical trials to better reflect the interests of patients and patient safety. In particular, the MHRAis progressing development of a more transparent, robust, world-leading regulatory regime for medical devices. This will prioritise patient safety, while ensuring the UK remains an attractive place to develop and introduce medical devices so that patients have access to safe products.

7.19 The MHRA has begun engagement with stakeholders within the life sciences and healthcare sectors on a proposed regulatory regime. To inform the position on how best to engage patients, the MHRA has asked members of the public how they think they could make the most impact related to development of the new regulations, and via involvement in future regulatory decisions.

7.20 The MMD Act includes powers for independent advice for medical devices to be put onto a statutory footing. An independent, statutory advisory committee for medical devices will be established to strengthen the vigilance system for medical devices and support structured decision-making and formalise accountability. How this might operate will be informed by public consultation and the learning from the Agency’s review of the current systems and processes associated with its Devices Expert Advisory Committee and its Expert Advisory Committees.

7.21 In addition, in January this year, additional legal requirements for registration of medical devices coming onto the GB market were introduced. This is a key first step towards building a dataset to support safety and surveillance of medical

devices. The Unique Device Identification will feed into the Medical Device Information System - see chapter 8 for further detail.

Next steps

7.22 As part of these discussions on the future regulatory framework, elements of international best practice that promote public health and patient safety are being identified and prioritised. This will be followed by a formal public consultation later in 2021, with the aim of delivering legislation to put in place a world-class regulatory system, by April 2022 with patients at its centre.

7.23 A review of the current systems and processes associated with the Devices Expert Advisory Committee will be undertaken, and changes implemented early next year, until it can be put on a statutory footing for the longer term.

Actions for Improvement

Regulation

7.24 Within the Actions for Improvement related to regulation, 4 actions are of relevance to the operation of the MHRA, set out below:

Action for Improvement	Government response
When making regulatory decisions on benefit and risk of medicines and medical devices, the MHRA should demonstrate how patient views have been taken into account.	**Accept.** as described in the section above on 'patient involvement', the has published a Public and Patient Involvement Strategy for public consultation, and is expanding its Patient Group Forum. The MHRA has also recently launched the Innovative Licensing and Access Pathway (ILAP) which will reduce the time to market for innovative medicines and will have meaningful involvement of patients at every stage. A 15-person pilot patient group has been set up to input on key stages and regulatory decision making. In March the Agency launched a pilot project for selected applications to collect evidence on patient involvement activities undertaken as part of the product development. Detailed analysis of the evidence will help the Agency to improve

Action for Improvement	Government response
	the quality of clinical drug development and future health outcomes **Next steps:** Publication of the MHRA's Public and Patient Involvement Strategy. The MHRA intends to set up a patient reference group that will be involved in decisions around the Innovation Passport and other aspects of delivering the Target Development Plan in the ILAP for innovative products in developments. The Commission on Human Medicines will involve patient representatives in the future to ensure the patient voice is a key part of the consideration and advice to the MHRA.
To aid public understanding the MHRA should give detailed reasons for its decisions if they differ from decisions made by another major international regulator.	**Accept in principle.** As the UK's Regulatory Authority, the MHRA may take regulatory different decisions from other regulators if it believes it is justified by the scientific evidence, patients' and experts' input and UK clinical practice. In such circumstances the MHRA aims to always clearly explain its rationale and the reasons for any differences when the views of other regulators are known. The MHRA has embedded this aim into our work in monitoring the COVID-19 vaccines in real-world use. The MHRA has worked in collaboration with other key partners in the health system to try and ensure that available safety data, and analysis of how this impacts on recommendations for use, is transparent; accessible and clearly understood in the context of the UK's public health situation, especially where MHRA advice differs from international regulatory bodies.
The Department for Health and Social Care (DHSC) should consider if an equivalent of the Commission on Human Medicines (CHM) is needed for devices.	**Accept.** The MMD Act includes powers for independent advice for medical devices to be put onto a statutory footing. An independent, statutory advisory committee for medical devices will be established to strengthen the vigilance system for medical devices and support structured decision-

Action for Improvement	Government response
	making and formalise accountability. How this might operate will be informed by public consultation and by the learning from the Agency's review of the current systems and processes associated with Devices Expert Advisory Committee (DEAC) and the Expert Advisory Committees. **Next steps:** The review of the use of DEAC will be completed within the next 3 months and by the end of quarter one in 2022 a revised shadow DEAC will be implemented until it can be put on statutory footing for the longer term.
In future we recommend careful consideration should be given to implementing risk mitigation strategies of international regulators on potential teratogens.	**Accept.** The MHRA is reviewing the requirements already in place in the UK and the EU for medicines known or suspected to be teratogenic. These will be considered in the context of the risk mitigation programmes of other regulators in order to develop a consistent approach. Stakeholder input and expert advice will be sought on the feasibility and risk proportionality of the proposed measures for use in the UK. **Next steps:** Stakeholder input and expert advice will be sought on the feasibility and risk proportionality of the proposed measures for use in the UK. Once agreed, UK guidance will be issued and amendments to risk mitigation for specific products will be requested, as appropriate.

Hormone Pregnancy Tests (HPTs)

7.25 Additionally, the 'Action for Improvement' related to HPTs is of relevance to the operation of the MHRA, set out below:

Action for Improvement	Government response
The MHRA and CHM need to review their Expert Working Group (EWG) processes, specifically: • whether they should consider proactively checking potential	**Accept in part.** The CHM Code of Practice, including the policy on conflicts of interest, has been reviewed to ensure it provides Ministers, patients and the public with the assurance that decisions made by

Action for Improvement	Government response
members' interests prior to their appointment • how to best support the involvement of affected and other lay individuals in EWG meetings, including both asking and answering questions at appropriate points of the meeting • whether an independent secretariat should be used for EWGs • whether EWG reports should be reviewed by an independent panel of experts	the Commission are impartial. The MHRA plans to consult on this. The MHRA will also be providing better support for patient representatives and work is underway to review where it has formal patient or public involvement on advisory committees and groups with a view to ensuring representation across all groups. There are no plans to create a new independent secretariat. MHRA staff provide secretariat support to the CHM and its expert groups. Secretariat staff do not participate in discussions or the decision-making process and the MHRA considers the current arrangement appropriate. The MHRA's new Governance Office will establish oversight of the secretariat functions and will ensure continued best practice. There are no plans to create a second independent panel of experts. The CHM is established in statute to give independent advice to Ministers. As it is already independent, the MHRA considers it is the appropriate body to review EWG reports. **Next steps:** Public consultation on a revised CHM code of practice is planned for July, this will cover conflicts of interest and the revised code will be implemented by December 2021.

8. The Medical Device Information System (MDIS)

8.1 **Recommendation 7 of the Report states:** *'A central patient-identifiable database should be created by collecting key details of the implantation of all devices at the time of the operation. This can then be linked to specifically created registers to research and audit the outcomes both in terms of the device safety and patient reported outcomes measures'.*

Government response: We accept this recommendation. We have already legislated for this through the Medicines and Medical Devices Act 2021, which creates a power for the Secretary of State to regulate for the establishment of a UK-wide Medical Device Information System (MDIS). Alongside developing regulations, over £11m has been set-aside for a package of work in 2021/22 involving partners across the healthcare system to scope, test and cost options for MDIS and other medical devices patient safety workstreams, as well as complete a business case for a 5-year programme of work .

8.2 The Report rightly identifies the need for the healthcare system to centralise and standardise the collection, retention and analysis of data for monitoring the safety and effectiveness of implantable medical devices.

8.3 In order to close the gap identified in the collection and analysis of this data, it is essential that the UK has a comprehensive system to ensure that implantable devices are effectively monitored and any issues affecting patient safety are responded to appropriately. For this reason, the government welcomes recommendation 7. The recommendation is timely and well considered, supporting an existing programme of work which the government initiated prior to the publication of the Report.

Legislating for MDIS under the Medicines and Medical Devices Act 2021

8.4 The government acted in June 2020 to amend the Medicines and Medical Devices Bill to introduce powers, now at section 19 of the Medicines and Medical Devices Act 2021(MMD Act), that enable the Secretary of State to make regulations for the establishment and operation of the Medical Device Information System by NHS Digital. The new statutory powers were necessary to allow NHS Digital to mandate the provision of key data in relation to implanted medical devices from NHS and private sector healthcare providers in England, as well as similar healthcare providers in the Devolved Administrations.

8.5 The government would like to thank the Devolved Administrations for providing Legislative Consent Motions to enable their participation in the MDIS, ensuring it has UK-wide benefit. The efficacy of the MDIS will be greatly strengthened by their continuing involvement in its development and the inclusion of data from their healthcare systems.

8.6 The work on MDIS builds on the important work already underway following the Secretary of State's direction to NHS Digital under which they are developing the Pelvic Floor Information System – as set out in chapter 4 on pelvic mesh.

8.7 Early work on the MDIS is progressing with regular engagement between NHSX, NHS Digital, NHSEI-GIRFT, DHSC, the Devolved Administrations, and a range of stakeholders to scope the MDIS and the regulations that will underpin it.

8.8 Officials from DHSC, NHSX, NHS Digital and NHSEI-GIRFT presented an update to the Patient Reference Group. The Group emphasised the need for effective engagement and the importance of empowering patients to provide their views on MDIS, both for the forthcoming consultation and via any informal consultation sessions. Effective engagement would also build trust and understanding, not only on how MDIS will work but also how data will be held and used to enhance patient safety. The Group also provided valuable practical suggestions on the key principles for how the MDIS should operate. The advice and suggestions of the Group will be included in developing the next steps of the MDIS.

Next steps:

8.9 The government welcomes the requirement in section 45 of the MMD Act to consult before making regulations regarding the establishment and operation of the MDIS. The government would like views from a wide variety of stakeholders and is currently planning to hold a public consultation on the MDIS regulations later in 2021. We then plan for finalised regulations for MDIS to come into force in 2022. In particular, we will continue to listen to the views and concerns of patients.

Delivering the Medical Device Information System

8.10 Based on interest expressed from provider/trust sites, several pilot and early adopter organisations will be selected to participate in the NHS Digital MDIS pilot programme. The aim of the pilots is to provide assurance that the capabilities, functionality, and processes of the information system are fit for purpose, particularly on an end-to-end basis and from a customer point of view. The pilots will also evaluate the feasibility, time, cost, risk, and performance of the information system and will include training participants and gathering data on

user problems. This will ensure that solutions to identified issues can be implemented prior to transitioning the information system into live service.

Next steps

8.11 The government is ambitious for what the MDIS can deliver. We want an information system which enhances patients' confidence, ensuring patients know that when they receive or are treated with an implantable medical device their details, information about the procedure, and the details of the device will be held securely. This information can be used to contact patients swiftly so that appropriate action can be taken should an issue with the device, or procedure, be identified.

8.12 We are fortunate in the UK to have exemplar registries with world-leading expertise which could provide a template for the analysis and review of devices to support roll-out across all specialities. In particular, the National Joint Registry and the Orthopaedic Data Evaluation Panel/Beyond Compliance, which works with implant manufacturers to assess the relative risk of any new product. These are widely regarded as setting international best practice in analysing outcomes for orthopaedic procedures.

8.13 MDIS will work securely in partnership with central patient records to ensure a whole system response to optimise patient care. As our work progresses, the government is considering how MDIS could be supported in England by simplifying the inputting of secure data for clinicians and other healthcare workers, including the use of scanning solutions and automated data capture in perioperative settings. We are also considering how MDIS could enable detailed analysis of patient outcomes based on the device used, to enhance clinician and patient decision making, utilising clinical expertise in NHSEI-GIRFT. This should also support early detection of safety issues, clinical improvement and better patient outcomes.

Actions for improvement

Regulation

8.14 Within the Actions for Improvement related to regulation, 3 actions are of relevance to the establishment of the MDIS, set out below:

Action for Improvement	Government response
Where the patient gives permission an adverse device report should be linked to	**Accept in principle.** The creation of the Medical Device Information System (MDIS)

Action for Improvement	Government response
the patient identifiable database of implanted devices.	will capture key information on the device implanted, the procedure and the hospital where the procedure was performed. We also expect that if for example a patient or healthcare professional wishes to report an adverse incident to the MHRA through the Yellow Card reporting scheme, data from MDIS will be able to assist by providing additional information in relation to the particular implanted device. Additionally, MDIS could assist clinicians in the reporting of events to MHRA relating to device revision. We have been working with NHS Digital to ensure that when a clinician inputs a revision in the pelvic floor registry, they are directed to the MHRA Yellow Card website to report the revision to the MHRA. A link to the Yellow Card scheme has now been added to the registry web form and is being tested. **Next steps:** The government is planning a public consultation later in 2021 on the MDIS regulations, and plans for finalised regulations for MDIS to come into force in 2022.
A public-facing Unique Device Identification (UDI) database for UK devices based on the Global Unique Device Identification Database (GUDID) should be scoped.	**Accept.** The MHRA recognises that there is an explicit need for devices registration data to be outward facing, to allow patients and the public to view and interrogate information about the safety of devices. The MHRA will achieve this by developing a UK medical devices registration / UDI system which will make identification of medical devices and related safety information more accessible to patients, the public and the health services, through its availability online. Work in the area is already underway and by the end of the year it will be a requirement under the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) that all medical devices, In vitro diagnostic (IVD) medical devices and custom-made devices are registered with the MHRA before being

Action for Improvement	Government response
	placed on the Great Britain market. Different registration arrangements exist for devices placed on the market in Northern Ireland. The Medicines and Medical Devices Act 2021 which received Royal Assent in February 2021, provides further powers to create a comprehensive devices registration / UDI system and disclose information held within the system to the public and others. The MHRA devices registration/UDI system will be the main source of medical device reference data for patients and the UK healthcare community including the NHS Digital Medical Device Information System (MDIS). **Next steps:** The MHRA is currently developing a formal public consultation on the future regulatory regime. The consultation is expected to take place this summer. The implementation of our new regime for medical devices will incorporate the revised MHRA devices registration/UDI system.
We recommend a publicly searchable database of adverse events for both medicines and devices.	**Accept.** The MHRA SafetyConnect programme will introduce a new and more responsive vigilance service to detect and respond to safety concerns with any medicine, medical device or blood product more quickly and more comprehensively than ever before. This will significantly improve how the MHRA monitors and acts on safety issues, through joined up safety vigilance, reporting and information. It will also improve how the system interacts with patients and make data available to patients. **Next steps:** The implementation of the MHRA's new adverse event reporting system will be completed by March 2022.

Databases and registries

8.15 The Report contains one ‘Action for Improvement’ related to databases and registries, set out below:

Action for Improvement	Government response
Databases and subsequent registries should embrace the private or independent health care sector as well as the NHS.	**Accept.** The government acted in June 2020 to amend the Medicines and Medical Devices Bill including powers, now section 19 of the Medicines and Medical Devices Act 2021, that enable the Secretary of State to make regulations for the establishment and operation of the Medical Device Information System by NHS Digital. The new statutory power enables NHS Digital to mandate the provision of key data in relation to implanted medical devices from NHS and private sector healthcare providers in England, as well as similar healthcare providers in the Devolved Administrations. This recognises that a number of procedures using implanted medical devices are carried out in the private sector, particularly for certain clinical specialities. It is therefore critical that the MDIS provides a comprehensive UK-wide system covering procedures carried out both by the NHS and private sector providers. Early work on the MDIS is underway with regular engagement between NHSx, NHS Digital, NHSEI-GIRFT, the Department of Health and Social Care (DHSC), the Devolved Administrations and a range of stakeholders, to scope the MDIS and the regulations which will underpin it. **Next Steps:** The government will continue engaging with stakeholders, including with the private healthcare sector, as the project develops. We have also worked with the Safety Review Patient Reference Group as part of our approach to ensure that we listen to the views and concerns of patients. The government plans a public consultation before the MDIS regulations are made.

Collecting and using data

8.16 The Report contains 3 Actions for Improvement related to collecting and using data, set out below:

Action	Response
Patient reported measures such as Patient Reported Outcome Measures (PROMs) and Patient Reported Experience Measures (PREMs) should become common currency in the assessment of the benefits and risks of current and new interventions.	**Accept.** Patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) are used to assess the quality of care delivered to NHS patients from the patient perspective. PROMS data has been collected by all providers of NHS-funded care since April 2009 and currently cover two clinical procedures: hips and knee replacements. The measures calculate the health gains after surgical treatment using pre- and post-operative surveys. They provide an indication of the outcomes or quality of care delivered to NHS patients and can help healthcare providers, commissioners and other stakeholders to make informed changes to their services. NHSEI is committed to embedding the patient voice in the design and delivery of healthcare. There are many ways in which programmes and interventions will include greater patient involvement to ensure better patient experience and patient outcomes. This may be though patient public involvement (PPI), co-production and input from those with lived experience within the design and delivery of services and/or though shared decision making at delivery. **Next Steps:** Patient surveys and questionnaires which give insight into the experience and outcomes of service users are vital in order for us to improve service delivery. Insights from national surveys such as those in primary care or maternity services are augmented by more bespoke questionnaires such as the Friends and Family Test (FFT), and those used within specific clinical improvement programmes such as the Cancer Quality of Life measure and other patient reported measures being developed, for example, for women

Action	Response
	considering a mesh implant. The various measures all come with costs, benefits and real-world implementation challenges that will need careful consideration. The most important thing is that patients receive high-quality care that delivers good outcomes and a positive experience.
Every interaction the patient has with a health service provider should be captured once only and by one or other data subset, ideally in the electronic health record. The NHS number should be included to enable those subsets to be linked.	**Accept.** The government will work closely with NHS Digital and partners, including in the Devolved Administrations, to consider how we best minimise the implications for providers when delivering a UK-wide Medical Device Information System (MDIS), which is addressed under recommendation 7. The government is committed to significantly reducing the burden on the front line in the NHS and private sector providers in England. Data collection via ADAPt /PHIN will be repurposed where possible to reduce burden. The Data Alliance Partnership (DAP) was formed last year at the request of the Secretary of State, which aims to facilitate the sharing of data across member organisations, thereby supporting a reduction in data collected from front line services. **Next Steps:** It is anticipated that the data collections from NHSEI for the MDIS and other interrelated elements such as patient safety and adverse incident reporting will be reviewed by the Data Alliance Partnership Board, looking at burden reduction and ensuring there are no duplications or gaps. This cross-service Board, and the measures being put in place to support it, will reassure the Health and Adult Social Care system that we are able to drive progress towards reducing burden swiftly and collaboratively.
Every child's NHS number should be entered on their school attainment record on year of entry.	**Accept in principle.** Teams across Government and in NHSx are working together to consider solutions to enable information-sharing with the aim of supporting local authorities and other

Action	Response
	agencies to identify and help vulnerable children and young people. This work may include linking data across health, education and care to identify children and young people who are known to services and at risk of harms and poor outcomes. Some of this work will explore how unique identifiers, such as NHS numbers, can be used effectively.

9. Conflicts of interest

Conflicts of interest

9.1 **Recommendation 8 of the Report states:** *'Transparency of payments made to clinicians needs to improve. The register of the General Medical Council (GMC) should be expanded to include a list of financial and non-pecuniary interests for all doctors, as well as doctors' particular clinical interests and their recognised and accredited specialisms. In addition, there should be mandatory reporting for the pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions and individual clinicians'.*

9.2 The Report concludes that transparency of interests needs to improve, and makes the case that responsibility for transparency of interests should lie with all relevant parties, including individual clinicians, manufacturers, regulators, and research journals. The government agrees with these sentiments – transparency is essential for patient trust and informed consent, and for ensuring the best possible outcomes in terms of patient safety and efficiency.

Government response*:* accept in principle. 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. We also agree with the second part of the recommendation, and we are exploring options to expand and reinforce current schemes.

9.3 Our response to recommendation 8 is in two, inter-dependent, parts. To address the first part of the recommendation, we will ensure it is a regulatory requirement that all registered healthcare professionals must declare their relevant interests, and that this information is meaningful and accessible for patients at a local level. This approach is underpinned by our response to the second part of the recommendation, which considers the options to expand the reporting of payments by industry to healthcare professionals and organisations, including in a mandatory system. The two parts, when read together, therefore, ensure the reporting of healthcare professionals' interests and industry payments are both transparent, accessible and mandatory. Together they ensure patients can make informed decisions about their treatment and care. The sections below detail our response to the two parts of the recommendation in turn.

Lists of doctors' interests

9.4 **The first part of recommendation 8 states**: *'Transparency of payments made to clinicians needs to improve. The register of the General Medical Council (GMC) should be expanded to include a list of financial and non-pecuniary interests for all doctors, as well as doctors' particular clinical interests and their recognised and accredited specialisms'.*

Government response: We accept this part of the recommendation in principle as we agree that doctors' interests should be declared and publicly available. Furthermore, we believe this should be extended to all registered healthcare professionals. We do not think that the GMC (or other regulator's) register is the best place to hold this information. We will ensure there is a regulatory requirement that all registered healthcare professionals declare their relevant interests, and that this information is published locally at employer level.

9.5 The government agrees that doctors' financial and non-pecuniary interests must be declared and publicly available. It is essential there is a culture in which all registered healthcare professionals are open and honest about their interests and agree it is vital that all patients can make informed decisions about their treatment and care. While we recognise that conflicts of interest may be unavoidable in complex healthcare systems, it is critical that all relevant financial and non-pecuniary interests are identified, declared, properly managed, and publicly available.

9.6 The government also believes that it is not just doctors who must declare their relevant interests, but rather all registered healthcare professionals. We are therefore going further than the recommendation, and we will make it a regulatory requirement that all registered healthcare professionals must declare their interests to their employer, contractor, or the organisation where they are providing services. The healthcare provider must then ensure that all declarations of interest are publicly available for patients at a local level.

9.7 It is crucial that any published list of interests is meaningful and accessible to patients at a local level. Our approach is for publications of interests to be held at a local level as patients know where healthcare professionals work and are more likely to seek information from the organisation that provides their treatment and care. All healthcare providers will be required to collect, monitor, and publish a list of their employee's interests in a prominent place on their website. Organisations without websites must maintain registers on-site, clearly available for patient review. We will continue to work with healthcare organisations across the NHS and independent sector to ensure there is appropriate implementation, governance, and enforcement of this approach.

9.8 The government believes that regulators' registers are not the best place to hold registrants' interests. The role of the regulator's register is to record specific information on a healthcare professional's qualifications and fitness to practise. Accessing regulators' registers also requires a knowledge of how healthcare professionals are regulated. A report by the Council for Healthcare Regulatory Excellence shows that many patients do not have this knowledge.

9.9 It is essential patients can easily access any publication of interests and are supported to interpret the information. At a local level, healthcare providers can also ensure there is meaningful oversight of any publication of interests. The interests of clinical decision-makers can be complex, and our approach ensures there will be local mechanisms in place to ensure patients have the necessary support to understand any relevant information. This accessibility, availability, and oversight of information will allow patients to make informed decisions about their treatment and care.

9.10 We are working with NHSEI and the Independent Healthcare Providers Network (IHPN) to ensure this approach is consistently applied across the NHS and independent sector. NHSEI has guidance that says all staff should declare their interests to their employer. The current guidance states providers should, as a minimum, publish the interests of decision-making staff. Decision-making staff are defined as those who influence how taxpayers' money is spent. We will work with NHSEI to extend the scope of this guidance so that it applies to all registered healthcare professionals. We will work with the IHPN to ensure guidance is distributed across the independent healthcare sector.

9.11 We have engaged with all professional regulators. Regulators will ensure their standards, guidance, and communications are clear that registrants must declare all of their competing and potentially competing interests. Each professional regulator has standards their registrants must adhere to. These standards set out the professional values, knowledge, skills and behaviours required of all healthcare professionals working in the UK. It is a requirement of all registered healthcare professionals' registration that they meet these standards. A failure to meet these standards, in a way that poses a risk to patient safety or public trust in registered healthcare professionals, will put registrants' registration at risk. The regulators will ensure this approach is effectively communicated to their registrants via appropriate channels. In addition, all healthcare regulators have committed to reviewing their joint statement on conflicts of interest. This sets out the expectations of how doctors and other professionals, working in healthcare, should act in relation to avoiding, declaring, and managing actual or potential interests.

9.12 We have worked with the Care Quality Commission (CQC) to ensure that implementation is monitored and that there is local accountability. Through its

ongoing monitoring of healthcare providers, the CQC will check that NHS and independent providers are collecting, maintaining and publishing their employee's interests in line with guidance. The CQC is also updating its guidance on the assessment methodology for its 'well-led' key question. We will work with the CQC to ensure the expectation for all healthcare providers to publish their employee's interests is included in this updated guidance. The CQC will make sure its assessment of healthcare providers is in line with any updated guidance on declarations of interests issued by NHSEI, GMC, and other relevant stakeholders. We will continue to work with the CQC to explore the options for publicising the findings from its assessments in this area.

9.13 We presented a working proposal of this response to a patient reference group. Participants' engagement and feedback on the proposal has informed our final response. Group members felt strongly that any registry of interests must be mandatory. In response, we have ensured it is a regulatory requirement that all registered healthcare professionals must declare their interests to their employer.

9.14 Group members stated professional healthcare regulators must take responsibility and act if registrants fail to declare their interests. We have worked closely with all professional healthcare regulators to ensure their responsibilities are clear. All professional healthcare regulators must have clear expectations and standards for registrants on how they declare and manage their interests. Regulators must also act when there is failure to meet those standards in a way that poses a risk to patient safety or public trust in regulated healthcare professionals.

9.15 Some Group members raised concerns around the implementation of our approach at a local level. This included specific questions around how temporary staff, such as; locums, bank staff and staff working under practicing privileges, declare their interests. We have adjusted our approach to be clear that any registered healthcare professional must declare their interests to their employer, contractor, or the organisation where they are providing services. The healthcare provider must then ensure that all declarations of interest are publicly available for patients at a local level.

9.16 The recommendations in the Report apply to England only. We have, however, worked closely with the Devolved Administrations and are in joint agreement that this will be a UK-wide approach to ensure consistency in transparency across the four nations. We are grateful to the Devolved Administrations for their advice and collaboration and will continue to work closely with them on implementation, particularly in relation to temporary staff and the independent sector.

Next steps:

9.17 Over the next 12 months, we will work to implement this approach through completing the following actions.

9.18 We will ensure that NHSEI guidance is updated to reflect all registered healthcare professionals. We will work with IHPN to ensure that the NHSEI guidance is clear and consistent across both the NHS and Independent sectors.

9.19 Continue to work with all professional healthcare regulators to ensure their standards show clear expectations of healthcare professionals in terms of declaring and managing interests.

9.20 Work with the Professional Standards Authority to ensure that all regulators develop and promote guidance on declarations of interests.

9.21 Work with the Care Quality Commission to create oversight and enforcement routes for both professionals and providers.

9.22 Continue to work with NHSEI, IHPN and NHS employers to monitor how our approach is implemented at a local level

Mandatory reporting for industry

9.23 **The second part of recommendation 8 states:** *'In addition, there should be mandatory reporting for the pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions and individual clinicians'.*

Government response: We accept in principle the need for stronger reporting in this part of recommendation 8. We support transparency of payments from industry, and we are exploring options to expand and reinforce current industry schemes, including making reporting mandatory through legislation.

9.24 The government agrees that transparency of medicine and medical device industry payments to relevant professionals and organisations is an important part of ensuring patient confidence. As with doctors' interests, it is important that this information is published and easily accessible for patients.

9.25 Regarding medicines, the existing industry scheme for medicines, Disclosure UK, is run by the Association of the British Pharmaceutical Industry and participation is a condition of their industry code of conduct. It is also used by non-members of

ABPI. It is comparable to schemes in other leading countries and has a strong level of industry participation.

9.26 However, the government has heard stakeholder concerns that the medicines sector Disclosure UK scheme is not supported by legislation. This means that clinicians' voluntary permission is usually sought for payment details to be published, and in a significant minority of cases, individual names are withheld. It is also difficult to establish that all relevant companies are included.

9.27 Regarding medical devices, the medical device sector does not have any formal scheme for transparency of payments, meaning that patients lack information on a highly important area of clinical decision-making.

9.28 We have engaged with the Patient Reference Group, MHRA, ABPI, and other industry stakeholders to better understand the strengths and weaknesses of current systems for medicines and medical devices, and to understand options to strengthen reporting for the medicines and to introduce reporting for medical devices.

9.29 We presented an update on our progress considering the recommendation to the patient reference group. The Group felt strongly that reporting for both the medicines and medical devices sectors should be mandatory, and should include a broad range of organisations, including medical device manufacturers. The Group also felt that it was critically important to patient transparency that information is accessible and user-friendly.

Next steps

9.30 We will work to further develop options for improving industry reporting requirements. We will investigate whether reporting and transparency in the current industry scheme for medicines could be improved by allowing the industry to publish clinicians' names without seeking their consent. We will explore options to make such reporting mandatory, including legislation. This will require further consultation with stakeholders on the detail.

9.31 We will continue to work with the devices industry and other stakeholders on the options for introducing reporting of payments for the medical devices sector. This will be a significant change, as no formal scheme currently exists. The government intends for this to give patients full confidence in the transparency of decision-making.

Actions for Improvement

Conflicts of interest

Action for Improvement	Government response
Organisations: Organisations should ensure clear governance arrangements to cover the potential conflicts of interests of any individual who participates in either regulatory activities or inquiries, including the composition of expert panels. Whilst it is to be expected that those people asked to participate should declare any potential conflicts of interest, the organisation itself has a responsibility to make its own enquiries.	**Accept.** The rules governing the identification and handling of conflicts of interest for the Commission on Human Medicine (CHM) and its Expert Advisory Groups are contained in the Commission on Human Medicines Code of Practice (the Code). The Code has been reviewed and is being updated with aim to provide Ministers, patients and the public with assurances that decisions are impartial and processes to manage conflicts are robust, transparent and allow for public scrutiny. **Next steps:** Key changes under consideration to achieve the above aims include: A description of the process as to how and when interests are proactively identified. The introduction of a ‘public register’ of interests, which will be accessed through the MHRA website and updated throughout the year. The establishment of a Conflicts Advisory Panel, which will interpret policy in the event that doubt arises regarding an interest. The Panel's decisions will be published. The creation of a new category of ‘invited expert’, which permits personal interests and outlines how the interest is managed. For example, the interest may be managed by excluding the individual from the discussion/decision but allowing questions from the members. This would strike a balance between allowing access to the best advice, while also protecting the impartiality of the

Action for Improvement	Government response
	committee. Extending the Code's scope to include Expert Working Groups and additional definitions for observers, invited experts and experts providing written advice who may not attend the meeting. A public consultation on a revised CHM code of practice is planned for July and the revised code will be implemented by December 2021.
Research: All journals should provide assurances to their readers that their Code of Practice relating to Conflict of Interest is compliant with the policy set out by the World Association of Medical Editors.	**Accept in principle.** The National Institute for Health Research (NIHR) and UK Research and Innovation (UKRI) strongly uphold the highest standards of rigour and integrity in all aspects of research. This includes enabling an environment where research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards. Both NIHR and UKRI are signatories to the Concordat to Support Research Integrity and work together with the other signatories to embed the principles across the sector. The Concordat also recognises the need for greater openness and transparency and to ensure the adherence to consistently high standards across the research community. Failures to disclose conflicts of interest are considered as research misconduct. More specifically, the NIHR Journals Library and the NIHR Open Research platform adhere to the International Committee of Medical Journal Editors (ICMJE) Conflict of Interest Disclosure policy in the management of conflict of interest in the publication of its titles. The ICMJE policy is internationally recognised in scholarly publication and is an equivalent to the World Association of Medical Editors policy that has been suggested.

Action for Improvement	Government response

Implementation and assurance of guidelines

9.32 The Report contains 4 Actions for Improvement related to implementation and assurance of guidelines, set out below:

Action for Improvement	Government response
Annual appraisal of doctors should include providing evidence of awareness of relevant guidance in the doctor's area of practice. Colleagues should report failure to follow guidance which is detrimental to patient safety. This should apply in the private or independent sector as well as in the NHS	**Accept.** All licensed doctors are required to participate in annual appraisals for revalidation and to collect supporting information about their practice as part of this process. It is the responsibility of the Responsible Officer to ensure that local processes are in place for raising and acting on concerns, with issues escalated to the GMC as appropriate. The GMC has published guidance on supporting information for appraisal and revalidation which sets out the GMC's requirements for the supporting information licensed doctors must collect, reflect on and discuss at appraisal for revalidation. In November 2020, the GMC revised its supporting information requirements to promote registrants' awareness of clinical guidelines. Quality improvement activities are one of the 6 types of supporting information required for appraisal. Doctors must be able to show they have participated in quality improvement activity that is relevant to all aspects of their practice. The guidance recognises that quality improvement can take many forms, including, 'identifying lessons for improvement and compliance with clinical guidelines' and reviewing the 'Audit of outcomes from clinical guidelines'. At a provider-level, in 2014, NHSEI published an updated version of the

Action for Improvement	Government response
	"Medical Appraisal Guide" which ensures that medical appraisals are carried out effectively, consistently and to a high standard. The guide was tested as part of an extensive programme of testing and piloting and should be read in conjunction with GMC guidance. In 2019, the Independent Healthcare Providers Network published its Medical Practitioners Assurance Framework (MPAF), for all medical practitioners working in independent healthcare settings. The MPAF states all medical practitioners are required to undertake an annual whole practice appraisal, which is focused around the GMC's Good Medical Practice and covers their whole scope of practice.
The GMC should be alert and act, if any doctor's practice causes concern in respect of failure to follow guidance.	**Accept.** The GMC state that serious or persistent failure to follow Good Medical Practice and all the guidance that stems from it, will ultimately put a doctor's registration and ability to practise at risk. Through their annual appraisal, doctors have a responsibility to demonstrate, through supporting information, that they are continuing to meet the principles and values set out in Good Medical Practice. It is the responsibility of the Responsible Officer to ensure that local processes are in place for raising and acting on concerns, with issues escalated to the GMC as appropriate. The GMC can only act when concerns are brought to its attention. The GMC's focus is, therefore, on promoting the reporting of concerns. Through the patient-facing website, the GMC can publicise and signpost the types of complaints it can investigate for patients. The GMC also encourages professionals to raise concerns through the creation of a 'Speaking Up Hub' for doctors, the development and piloting of a 'Professional behaviours and patient safety' training programme, and the

Action for Improvement	Government response
	development of the 'Supporting a profession under pressure programme' The GMC proactively scans media stories to identify issues and can initiate referrals based on this information. The GMC can also open a fitness to practise investigation if it receives intelligence about potential concerns through its outreach services.
Hospitals should encourage clinical audit and should have robust systems for monitoring quality at Board level. The Care Quality Commission (CQC) should also assure itself that hospitals both in the NHS and in the private sector, have robust quality assurance programmes including following appropriate guidance.	**Accept.** CQC is committed to ensuring that people's care, treatment and support achieves good outcomes, promotes a good quality life and is based on the best evidence available. Furthermore, the CQC expects that people's care and outcomes are robustly monitored and that providers routinely assess their outcomes with other similar services. CQC's published framework for healthcare services asks a number of key questions when assessing healthcare providers, including whether the provider regularly collects and monitors information on patient outcomes and participates in quality improvement activities, such as clinical audits. The framework is also supplemented by CQC's "Well-led Framework", which requires all healthcare providers to undertake improvement activity. The National Clinical Audit and Patient Outcomes Programme (NCAPOP) is made up of 40 plus clinical topics that support the delivery of several priorities and statutory duties. These duties and priorities include monitoring and stimulating quality improvement in care, in line with NHSEI's clinical corporate priorities, as set out in the "NHS Long Term Plan". Participation in these programmes is mandated through the NHS Standard Contract. There is also

Action for Improvement	Government response
	an additional number of national audits that organisations should sign up to and report via their Quality Accounts requirement (or Quality Reports with respect to Foundation Trusts). Assurance committees within NHS trusts, who report into the trust board, monitor compliance with national audit programmes to support existing operational quality improvement strategies. Trusts should have a programme of clinical audit that balances both national and local audits, in addition to local intelligence, outcomes or incidents that have occurred within the trust. The CQC also expects trusts systematic programme of clinical and internal audit to monitor quality, operational and financial processes to identify where action should be taken. Details of the programme should be reported, for assurance purposes, to the quality committee and the trust board.
Those responsible for introducing new procedures should factor in the particular responsibilities of clinicians and organisations to monitor risks during this period, including the training time taken to acquire the necessary competencies and skills.	**Accept in principle.** NICE has provided advice on how to safely introduce new procedures into clinical practices. This has been endorsed by the NHS in all 4 nations and is available via the NICE website. NICE advises that any clinician undertaking a procedure must have the appropriate training and have the relevant experience to do so. However, the responsibility for training programmes falls within the remit of the Medical Royal Colleges.
When the system has monitored guidance or standards, and identified an issue, there must be clarity on who is responsible for co-ordinating action, and sufficient support and resource for implementation of remedial action.	**Accept in Principle.** Compliance with patient safety guidance or standards and actions taken by regulators or commissioners in cases of non-compliance are key to ensuring safe practices and improvements to patient safety. For example, the CQC has a key responsibility in the overall assurance of

Action for Improvement	Government response
	levels of safety and quality of health and adult social care services. Under the Health and Social Care Act 2008, all providers of regulated activities, including NHS and independent providers, must register with the CQC and follow a set of fundamental standards of safety and quality below which care should never fall. The CQC can take enforcement action to prevent any further harm or risk of harm to patients and other members of the public. Any organisation that issues guidance and/or sets standards should consider the efficacy of that guidance or standards in order to support cases of non-compliance being identified and responded to as appropriate. As a result of different guidance and standards having, for example, differing issuing bodies, evidence bases and levels of obligation, the government does not consider that a single mechanism of assurance would be practical.

10. Implementation and next steps

10.1 **Recommendation 9 of the Report states that:** *'the government should immediately set up a task force to implement this review's recommendations. Its first task should be to set out a timeline for their implementation'.*

Government response: We accept this recommendation in part. We have no current plans to establish an independent task force to implement the government response. We have already established a Patient Reference Group to work with the Department to develop this response.

10.2 As set out in the Written Ministerial Statement of 11 January 2021, the government has no plans to establish an independent task force to implement the Report's recommendations. As is standard practice with independent reviews and inquiries, once a report is published it is passed to the government in order to consider the insight it provides and how the recommendations might be taken forward. Since the report's publication, the Department has coordinated intense work across the health and care system, as this response makes clear. This response demonstrates the scale and breadth of work underway to respond to this important report since it was commissioned in 2018.

10.3 As set out in chapter 2 on patient voice and patient safety, the government accepted the second part of recommendation 9, for the establishment of a patient reference group.

Implementation of the government response

We will aim to publish an update on progress implementing the government response in 12 months' time. This Report presents a powerful programme for change – one which this government is committed to see complete.

10.4 There is no doubt that the health system took too long to listen, and to respond to the families affected by Primodos, sodium valproate and pelvic mesh. We hope that the actions outlined in this response will give patients and the broader public the confidence that the system is committed to building back trust.

10.5 This response sets out an ambitious and comprehensive programme of work to deliver real improvements in patient safety and how the system listens to patients. As the Report sets out so clearly, these two aims are complementary, and patient voice must be central to efforts to improve patient safety. we

10.6 Much of this response concerns work that is in its early stages, and, we know there is more work to be done. Understandably, we anticipate that there will be a high level of interest in the progress of the numerous programmes of work as they develop.

10.7 The section below sets out key deliverables over the next 12 months.

Patient safety commissioner

- conclusion of the public consultation in August 2021 on the proposed legislative details that will govern the appointment and operation of the Commissioner

- drafting of regulations on the appointment of the Commissioner

- launch of a campaign to fill the Commissioner position; appointment of England's first Patient Safety Commissioner in 2022

Pelvic mesh

- establishing a regional service in the South West NHS region in 2021

- annual Clinical Summit to present data and discuss outcomes, which includes surgical and non-surgical outcomes and patient feedback

- development of an interim PROM for piloting in 2021 ahead of development of a validated PROM for pelvic floor by 2023

- initiation of retrospective audit by December 2021 for publication by July

Sodium valproate

- publication of the second report from the valproate registry by September 2021

- building and integration of a digitalised annual risk acknowledgement form into the registry to fully monitor adherence to the Pregnancy Prevention Programme by early 2022

- in 2021 the valproate registry will be expanded to include other anti-epileptic drugs. At a later stage, women will be able to input data themselves

- expansion of the valproate registry to the whole of the UK. Initial scoping work will begin in 2022

MHRA reform

- publication of a Public Engagement and Involvement Strategy, and new processes embedded in 2022

- review and improve patient representation across all decision-making committees, to ensure there is patient representation across all, with training provided. This is linked to the expansion of the Patient Group Consultative Forum

- completion of a public consultation on a revised Committee on Human Medicine code of practice, which will cover conflicts of interest, will take place in summer 2021. Subsequent implementation of a revised code by the end of 2021

- implementation of improvements to adverse event reporting systems completed by March 2022

- implementation of a new regulatory framework for medical devices by April 2022

- changes to the Devices Expert Advisory Committee arising from the review

- introduction of statutory provisions for the establishment of publicly held medicines registries

Medical Device Information System

- in 2021, a public consultation on the regulations to be made under section 19 of the Medicines and Medical Devices Act 2021

- alongside developing regulations, a package of work is underway to build, test and cost options for how an MDIS could be embedded into the UK healthcare system, as well as complete a business case for a 5-year programme of work

Conflicts of Interest

- implementation of lists of clinicians' interests held at employer level, working with stakeholders to monitor and evaluate implementation, within the next 12 months

- investigating whether reporting and transparency in the current industry scheme for medicines could be improved by allowing the industry to publish clinicians’ names without seeking their consent. We will explore options to make such reporting mandatory, including legislation

- we will continue to work with the devices industry on the options for clear reporting in that sector – recognising this will be a significant change, as no formal scheme currently exists. The government intends for this to give patients full confidence in the transparency of decision-making

Annex A: Actions for Improvement reference table

The table below contains the full list of Actions for Improvement contained in the Report of the IMMDS Review, along with the page reference as to where they are responded to in the government response.

	Theme 3: Informed Consent	
1	Information should be conveyed to patients in a way that is clear and meaningful. The opportunity to speak to, or hear from, others who have undergone the same intervention should be considered.	P17
2	A single patient decision aid (or core set of information) should be produced for each surgical procedure or medical intervention, co-designed by patients and clinicians. The National Institute for Health and Care Excellence (NICE) should take the lead on facilitating this.	P17
3	Patient-clinician consultations about consent must be proportionate to the circumstance and appropriately documented. Both the patient's and clinician's concerns and comments should be recorded. Where appropriate and with the agreement of both parties, conversations around consent should be audio or video recorded to allow the patient to take it away and reflect upon it. In future a copy of this discussion should be stored on the patient's electronic record.	P18
	Theme 4: Redress	
4	There is a need for additional training for those carrying out assessments for DWP based on the insight condition reports. This should help those carrying out the assessments to make equitable decisions.	P25
	Theme 5: Complaints	
5	Patients across the NHS and private sector must have a clear, well publicised route to raise their concerns about aspects of their experiences in the healthcare system. It will be for the	P19

	Theme 5: Complaints	
	implementation task force (see Recommendation 9) to address this problem.	
6	The time bar on GMC investigations should not be a barrier to establishing a pattern of poor practice by any one clinician.	P20
7	The bodies that have received complaints about the interventions under review should reassess what they have been told and satisfy themselves that they have taken necessary steps to identify any patterns and trends. They should inform the relevant organisations and Patient Safety Commissioner of outcomes of concern.	P21
8	Organisations who take complaints from the public should designate a non-executive member of the board to oversee the complaint handling processes and outcomes, and ensure that appropriate action is taken.	P22

	Theme 7: Conflicts of Interest	
9	Organisations: Organisations should ensure clear governance arrangements to cover the potential conflicts of interests of any individual who participates in either regulatory activities or inquiries, including the composition of expert panels. Whilst it is to be expected that those people asked to participate should declare any potential conflicts of interest, the organisation itself has a responsibility to make its own enquiries.	P80
10	Research: All journals should provide assurances to their readers that their Code of Practice relating to Conflict of Interest is compliant with the policy set out by the World Association of Medical Editors.	P81

	Theme 8: Guidelines - Implementation and Assurance	
11	Annual appraisal of doctors should include providing evidence of awareness of relevant guidance in the doctor’s area of practice. Colleagues should report failure to follow guidance which is detrimental to patient safety. This should apply in the private or independent sector as well as in the NHS.	P82

	Theme 8: Guidelines - Implementation and Assurance	
12	The GMC should be alert and act, if any doctor's practice causes concern in respect of failure to follow guidance.	P83
13	Hospitals should encourage clinical audit and should have robust systems for monitoring quality at Board level. The Care Quality Commission (CQC) should also assure itself that hospitals both in the NHS and in the private sector, have robust quality assurance programmes including following appropriate guidance.	P84
14	Those responsible for introducing new procedures should factor in the particular responsibilities of clinicians and organisations to monitor risks during this period, including the training time taken to acquire the necessary competencies and skills.	P85
15	When the system has monitored guidance or standards, and identified an issue, there must be clarity on who is responsible for co-ordinating action, and sufficient support and resource for implementation of remedial action.	P85
	Theme 9: Collecting and Using Data	
16	Patient reported measures such as Patient Reported Outcome Measures (PROMs) and Patient Reported Experience Measures (PREMs) should become common currency in the assessment of the benefits and risks of current and new interventions.	P71
17	Every interaction the patient has with a health service provider should be captured once only and by one or other data subset, ideally in the electronic health record. The NHS number should be included to enable those subsets to be linked.	P72
18	Every child's NHS number should be entered on their school attainment record on year of entry.	P72
	Theme 10: Database and Registries	
19	Databases and subsequent registries should embrace the private or independent health care sector as well as the NHS.	P70

	Theme 11: Regulation	
20	When making regulatory decisions on benefit and risk of medicines and medical devices, the MHRA should demonstrate how patient views have been taken into account.	P61
21	To aid public understanding the MHRA should give detailed reasons for its decisions if they differ from decisions made by another major international regulator.	P61
22	The Department for Health and Social Care (DHSC) should consider if an equivalent of the Commission on Human Medicines (CHM) is needed for devices.	P62
23	Where the patient gives permission an adverse device report should be linked to the patient identifiable database of implanted devices.	P67
24	A public-facing Unique Device Identification (UDI) database for UK devices based on the Global Unique Device Identification Database (GUDID) should be scoped.	P68
25	We recommend a publicly searchable database of adverse events for both medicines and devices.	P69
26	In future we recommend careful consideration should be given to implementing risk mitigation strategies of international regulators on potential teratogens.	P62
27	We recommend the creation of a system-wide healthcare intelligence unit to facilitate early signal detection which would draw on various sources of information, including issues raised by the patient safety commissioner.	P16
	Hormone Pregnancy Tests	
28	The MHRA and CHM need to review their Expert Working Group (EWG) processes, specifically: • whether they should consider proactively checking potential members' interests prior to their appointment • how to best support the involvement of affected and other lay individuals in EWG meetings, including both asking and answering questions at appropriate points of the meeting • whether an independent secretariat should be used for	P63

	Hormone Pregnancy Tests	
	EWGs • whether EWG reports should be reviewed by an independent panel of experts	

	Valproate	
29	An indicator on safe prescribing in pregnancy should be introduced for future iterations of the Quality and Outcomes Framework (QOF).	P51
30	In our view, a clear process should be agreed to ensure women are able to get appropriate counselling related to their epilepsy treatment and contraceptive choices.	P52
31	Information should be collected to identify those already affected by exposure to valproate in utero to ensure they have access to diagnosis and support, and to plan service provision.	P53
32	A prospective registry should be established for all women on anti-epileptic drugs who become pregnant, to include mandatory reporting of data relating to them and their child(ren) collated over lifetimes. This registry could potentially be expanded to collect data on paternal and transgenerational effects.	P53
33	The relevant stakeholders should continue to work with patient groups to monitor and improve the Pregnancy Prevention Programme and to consider the next steps, which should include NHS England and NHS Improvement (NHSEI) writing directly to all women and girls of childbearing potential, asking them to see their general practitioner or specialist.	P53
34	Clinicians should continue to follow guidance regarding prescribing of valproate and alternatives for all indications.	P54
35	A system similar to the Pregnancy Prevention Programme should be used where teratogenicity is well-known or the effects are severe. Alternatively an acknowledgement of risk form should be attached to the prescribing and/or dispensing of all medication considered to have teratogenic potential or known to have a risk above that of the general population.	P54

	Mesh	
36	Further research is urgently needed so that a clearer view can be reached on the inherent properties and safety of pelvic mesh.	P33
37	Medical device manufacturers must research and develop a remedial strategy to address any severe complications caused by their product. This strategy should be set out in the Instructions for Use (IFUs) and guidance. The strategy should be developed collaboratively with appropriate input from others, such as the regulators and the commissioners of any services required to carry out actions.	P34
38	We recommend that when a device or procedure is introduced a cohort of early recipients undergo enhanced reporting to detect unexpected adverse impacts.	P34
39	NICE's most recent guidance states that the Transvaginal Tension Free Vaginal Tape-Obturator (TVT-O) should not be offered routinely. In the future, we feel the TVT-O should only be used in exceptional circumstances, if at all.	P35
40	Professional bodies should lead on ensuring surgeons only operate within their capabilities. They must provide guidance for their members and ensure that surgeons are appropriately trained, and this should be assured through the appraisal process.	P36
41	A culture must exist where all multi-disciplinary team (MDT) members feel able to speak up and that their input will be listened to. Trusts must work to create a culture that facilitates effective MDTs.	P37
42	Conservative measures must be offered to women before surgery. We have heard that specialist pelvic floor physiotherapy cannot match the current demand. The service commissioner should identify gaps in the workforce and notify specialist clinicians, professional organisations and Royal Colleges. A co-ordinated strategy can then be developed to remedy the gap.	P37
43	Clinicians must ensure patients have sufficient understanding of their treatment including the benefits, the potential risks it presents, and the alternative treatment options, including doing nothing, in order to decide whether they are willing to have that treatment.	P38
44	Clinicians need to establish and agree terminology and definitions related to both mesh insertions and removals.	P39

	Mesh	
45	An audit to establish complication rates should be attempted using the women who had mesh insertions in 2010.	P40
46	A consensus needs to be reached on whether it is better to carry out full or partial removals. This is a clinical matter, and it must be done collaboratively, including consulting international experts. This consensus should be validated by carrying out follow up on those who have removals at the specialist centres. We strongly recommend that NICE actively monitor the situation and update their guidance promptly once a consensus has been reached.	P40
47	Consideration should be given to credentialing a small number of centres and surgeons for particular complex pelvic mesh surgeries.	p41
48	A remote counselling service along the lines we set up during this Review should continue to exist.	P42
49	Pelvic floor education should be encouraged, where appropriate, in schools and certainly in antenatal classes. In addition, we recommend that the NHS adopts the French model for universal post-natal pelvic floor rehabilitation.	P42
50	Dismissive, defensive attitudes by surgeons are a cultural issue that needs to be addressed by the medical profession, its professional bodies and regulators.	P43

Published to GOV.UK in pdf format only.

[Directorate/Division/Branch]

www.gov.uk/dhsc