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Policy paper

Independent Medicines and Medical Devices Safety Review: update report on government implementation

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Applies to England

Contents

9. Conflicts of interest

This publication is available at https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-update-report-on-government-implementation/independent-medicines-and-medical-devices-safety-review-update-report-on-government-implementation

Ministerial foreword

In July 2020, the Independent Medicines and Medical Devices Safety Review (https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-report) laid bare the consequences of a healthcare system that does not listen to the experiences of women. It made for difficult and sobering reading, and I would again like to thank Baroness Cumberlege and her team for their work and dedication to bring these issues to light.

The government's response to the review (https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-government-response) accepted the majority of the 9 strategic recommendations and the vast majority of the 50 actions for improvement. We also committed to publishing an update after one year on our progress in implementing those commitments. This document sets out this progress.

We have made good progress on all fronts, including the appointment of Dr Henrietta Hughes as England's first Patient Safety Commissioner (https://www.gov.uk/government/news/first-ever-patient-safety-commissioner-appointed). NHS England has set up 9 specialist centres across England to provide comprehensive treatment for women affected by implanted mesh, and the Medicines and Healthcare products Regulatory Agency (MHRA) has further tightened the restrictions around prescribing of sodium valproate.

We have also set out our wider ambitions for women's health in the first ever Women's Health Strategy for England (https://www.gov.uk/government/publications/womens-health-strategy-for-england). The strategy sets an ambitious agenda for boosting health outcomes for women and girls, and improving the way in which the health and care system listens to women's voices, and is informed by insight provided by the nearly 100,000 individual responses to the call for evidence (https://www.gov.uk/government/consultations/womens-health-strategy-call-for-evidence) held in 2021. We have also appointed Dame Professor Dame Lesley Regan as the Women's Health Ambassador for England (https://www.gov.uk/government/news/dame-lesley-regan-appointed-womens-health-ambassador) to lead work to tackle taboos around women's health and support implementation of the strategy.

We will continue to implement the small number of remaining commitments. We know that there is still more to do to make sure that the health and care system is safe – including further bringing down the number of pregnancies exposed to sodium valproate and having more women treated in specialist mesh centres.

The work outlined in this document demonstrates that we are working hard to re-establish trust in the healthcare system. We have listened, we have learnt and we will continue to work to make the healthcare system safer for women.

The Rt Hon Steve Barclay MP, Secretary of State for Health and Social Care

Maria Caulfield MP, Parliamentary Under Secretary of State (Minister for Mental Health and Women's Health Strategy) and Parliamentary Under Secretary of State (Minister for Women)

1. Introduction

Background to the Independent Medicines and Medical Devices Safety review

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
- how to make sure communication between the different groups involved is good

The report of the Independent Medicines and Medical Devices Safety review (https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-report) ('the review') was published on 8 July 2020. It contained 9 strategic recommendations and 50 actions for improvement.

The government response – July 2021

On 11 January 2021, the government published an interim response to the review (https://www.gov.uk/government/speeches/update-on-the-governments-response-to-the-independent-medicines-and-medical-devices-safety-review).

A full government response (https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-government-response) ('the 2021 response') was published on 21 July 2021.

The government accepted the overarching conclusion of the review that the system failed to listen to patients or to put patients at the centre of their care. We accepted 4 of the 9 strategic recommendations in full, one in principle and one in part. We also accepted 46 of the 50 actions for improvement in full or in principle, one in part and one remained under consideration.

We also committed to publishing a one-year implementation update on progress made to implement the accepted strategic recommendations and actions for improvement. This report delivers on that commitment.

A summary of progress

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."

Progress update

Complete.

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."

Progress update

Complete.

The government appointed Dr Henrietta Hughes as the Patient Safety Commissioner on 12 July 2022.

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."

Recommendation 4

" Separate schemes should be set up for each intervention – HPTs [hormone pregnancy tests], 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."

Progress update

We did not accept recommendations 3 and 4 because our priority is to make medicines and devices safer, and the government is pursuing a wide range of activity to further this aim.

NHS Resolution has launched 2 claims gateways on their website to provide further support to patients who may wish to bring a clinical negligence claim in relation to pelvic mesh and sodium valproate.

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."

Progress update

Complete for specialist mesh centres.

There are now 9 specialist centres in operation in England, which ensures that women in every region have access to these services. Each mesh centre is led by a multidisciplinary team to ensure patients get access to the specialist care and treatment that they need, including pain management and psychological support.

Ongoing for medicines in pregnancy.

Our view was that a network of new specialist centres is not the most effective way forward to help those adversely affected by medicines taken during pregnancy. NHS England has instead taken forward work to improve care pathways for children and families adversely affected by medicines in pregnancy.

Ongoing for sodium valproate.

The MHRA is introducing stronger regulatory measures to continue to reduce the number of pregnancies exposed to sodium valproate, including new patients under 55 years of age needing 2 specialists to document that no other medicine is effective or tolerated.

Work continues to improve compliance with regulatory measures. The MHRA and NHS Digital established the Medicines and Pregnancy Registry (https://digital.nhs.uk/data-and-information/publications/statistical/mi-medicines-and-pregnancy-registry) to track NHS prescriptions of valproate in girls and women of childbearing age in England.

In 2022 to 2023, an audit will be carried out by pharmacies to measure adherence to MHRA regulations.

Recommendation 6

> “ The 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.”

Progress update

Ongoing.

The MHRA has embarked upon an ambitious organisation-wide transformation to ensure it becomes a progressive and responsive patient-focused regulator of medical products.

It has been establishing a new organisational structure that improves how it listens and responds to patients and the public, developing a more responsive system for reporting adverse incidents, and strengthening 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.”

Progress update

Ongoing.

In 2021 to 2022, a scoping exercise was undertaken to determine how best to deliver this recommendation. This provided a significant amount of learning.

We concluded that, for England, expanding the coverage and breadth of existing registries will best deliver harmonised data collections that contain patient, device and outcome-level data. We have an ambitious target to increase registry coverage from 15% to 80% over the next 3 years.

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

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.”

Progress update

Ongoing.

We are currently piloting systems for doctors to declare their interests in NHS and independent settings across the UK. Full implementation will begin in 2023, subject to a successful review of the pilot systems. Once we have a system in place for doctors, we will consider systems for other healthcare professionals.

We legislated through the Health and Care Act 2022 (https://www.legislation.gov.uk/ukpga/2022/31/contents/enacted) to enable the Secretary of State for Health and Social Care to make regulations requiring companies to publish or report information about their payments to the healthcare sector. The government is reviewing the information gathered from stakeholders to develop plans on how best to deliver on the objectives of this recommendation.

Recommendation 9

The government should immediately set up a taskforce to implement this review’s recommendations. Its first task should be to set out a timeline for their implementation.

Progress update

We did not accept the recommendation to establish an independent taskforce to implement the government response.

We instead established a Patient Reference Group to inform work to develop the 2021 government response. The Patient Reference Group published an independent report on their work in July 2021. (https://www.gov.uk/government/publications/the-independent-report-of-the-patient-reference-group-response-to-the-immds-review-report)

2. Putting patient voice at the centre of patient safety

Patient Safety Commissioner

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 (https://www.legislation.gov.uk/ukpga/2021/3/enacted).

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.

Progress update

On 12 July, the government announced the appointment of Dr Henrietta Hughes as the Patient Safety Commissioner (https://www.gov.uk/government/news/first-ever-patient-safety-commissioner-appointed). Dr Henrietta Hughes started in post on 12 September 2022.

The government believes that patient voice must be central to everything the healthcare system does.

We introduced legislation via the Medicines and Medical Devices Act 2021 to establish a Patient Safety Commissioner.

We held a public consultation on the proposed legislative details that will govern the appointment and operation of the commissioner (https://www.gov.uk/government/consultations/the-appointment-and-operation-of-the-patient-safety-commissioner), as required by the Medicines and Medical Devices Act. This consultation was open from February to August 2021 and the consultation response was published on 6 January 2022.

The campaign to fill the commissioner position was launched at the beginning of this year in line with the public appointments process and closed on 1 February 2022.

On 20 June 2022, the government announced Dr Henrietta Hughes as its preferred candidate for the role. Following confirmation by the Health and Social Care Committee, she was appointed to the role in July and started in post on 12 September 2022.

The commissioner initially has a 3-year term of office and may be re-appointed for a further 3 years subject to ministerial agreement. This is in line with most other public appointments. This means that, if re-appointed, the post-holder could serve up to 6 years.

The commissioner will be an independent champion for patients. The commissioner's core role will be to promote the safety of patients, and the importance of the views of patients in relation to medicines and medical devices.

Actions for improvement

Action for improvement	Progress
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.	Government accepted this action in principle. We will work with the new Patient Safety Commissioner to address any concerns that they raise around the safety of medicines and medical devices. We acknowledge how the role of a system-wide healthcare intelligence unit could safeguard the interests of patients and other members of the public, and will continue to consider this matter.
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.	Government accepted this action. In relation to the GMC's guidance on Decision making and consent (https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent), the GMC updated its patient-facing webpage Patient guides and materials (https://www.gmc-uk.org/ethical-guidance/patient-guides-and-materials) in summer 2021. The GMC has also collaborated with the Personalised Care Institute to promote this new guidance and the National Institute for Health and Care Excellence (NICE) guideline [NG197] on shared decision making (https://www.nice.org.uk/guidance/ng197) (published June 2021). As part of its consent implementation work, the GMC has

Action for improvement	Progress
	published a case study on sodium valproate (https://www.gmc-uk.org/ethical-guidance/learning-materials/risks-of-sodium-valproate). The case study is designed to support implementation of GMC guidance by showing how to apply guidance on decision-making and consent within a specific context and is a means to highlight the risks of taking sodium valproate during pregnancy. It is also intended to promote the MHRA's strengthened regulatory position around sodium valproate. The case study was developed jointly with the Nursing and Midwifery Council (NMC), General Pharmaceutical Council (GPhC) and several patient groups. The GMC has also created an interaction learning tool that contains scenarios around consent, based on feedback from international medical graduate doctors who have asked for further guidance in this area. The GMC interactive learning tool is available on a range of different platforms including virtual reality and has been shared with all doctors who have signed up to the Professional and Linguistic Assessments Board Part 2 clinical exam. We will continue to work with all professional regulators during the implementation of recommendation 8a of the review. During the implementation phase of recommendation 8a, we will encourage professional regulators to consider this action when they individually review their codes, standards and 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. NICE should take the lead on facilitating this.	Government accepted this action in principle. NICE has undertaken a programme of work to promote and support shared decision-making, which includes producing patient decision aids. NICE is working closely with NHS England (NHSE) to encourage implementation of the shared decision-making guideline [NG197] (https://www.nice.org.uk/guidance/ng197), and has undertaken work to raise awareness of it among healthcare professionals and leaders across healthcare settings. This includes webinars for health professionals and the wider healthcare system (https://www.youtube.com/c/niceorguk). NICE has also promoted the guideline through the NICE medicines and prescribing associates (https://www.nice.org.uk/about/nice-

Action for improvement	Progress
	communities/medicines-and-prescribing/nice-medicines-and-prescribing-associates) network. As set out in section 4, patient decision aids have been developed and published to support NICE guidance [NG123] on urinary incontinence and pelvic organ prolapse in women: management (https://www.nice.org.uk/guidance/ng123). These aids will help women and their healthcare professionals discuss the different types of surgery for these conditions and make decisions that are right for each woman. NICE has also developed a standards framework for shared-decision-making support tools, including patient decision aids (https://www.nice.org.uk/corporate/ecd8). This framework sets out a series of standards to support people using patient decision aids in assessing the usefulness and quality of a patient decision aid. Furthermore, the framework is also useful to organisations who are developing patient decision aids, enabling them to undertake a self-assessment of the quality of their tools and processes. NICE and NHSE are considering the feasibility of creating a library of patient decision aids and support tools that have been produced by other bodies.
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,	Government accepted this action. The GMC's revised guidance on Decision making and consent (https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent) came into effect in November 2020. The GMC guidance reaffirms that serious harm can result if patients are not listened to, or if they are not given the information they need – and time and support to understand it – so they can make informed decisions about their care. Doctors must give patients the information they want or need to make a decision, and it must be shared in a way that they can understand and retain, so that they can use it to make a decision. An accurate record of the exchange of information leading to the decision should be captured in the patient's record, together with the decision made and any actions agreed. The GMC provides specific guidance on Making and using visual and audio recordings of

Action for improvement	Progress
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.	patients (https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/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's patient-facing webpage Patient guides and materials (https://www.gmc-uk.org/ethical-guidance/patient-guides-and-materials) was updated in July 2021. This webpage includes a section on 'decision-making and consent' that sets out how doctors should have conversations with patients. NHSE commissioned the Professional Records Standards Body to develop a draft shared decision making and consent standard (https://theprsb.org/standards/shareddecisionmakingstandard/), which is now complete. Endorsement is in progress for the draft standard and details will be published on the Professional Records Standards Body webpage when this work is complete.
Patients across the NHS and private sector must have a clear and well publicised route to raise their concerns about aspects of their experiences in the healthcare system. It will be for the implementation taskforce (see recommendation 9) to address this problem.	Government accepted this action. The new Patient Safety Commissioner will promote the patient voice in the context of medicines and medical devices. The GMC continues to support patients who have made a complaint through its Patient Liaison Service (https://www.gmc-uk.org/concerns/supporting-you-with-your-concern/patient-liaison-service). The Parliamentary Health Service Ombudsman makes final decisions on complaints that have not been resolved by NHSE, UK government departments and other public organisations. The ombudsman is currently piloting the NHS Complaint Standards (https://www.ombudsman.org.uk/complaint-standards), setting out in one place the ways in which the NHS should handle complaints. The Independent Sector Complaints Adjudication Service has worked with the Parliamentary Health Service Ombudsman on these standards and included them in their own code of practice for independent providers.

Action for improvement	Progress
The time bar on GMC investigations should not be a barrier to establishing a pattern of poor practice by any one clinician.	Government accepted this action. The Department of Health and Social Care (DHSC) is currently modernising the legislation that governs professional regulators. We consulted in 2021 on proposals for reform, including the proposal to remove the 5-year rule in Regulating healthcare professionals, protecting the public (https://www.gov.uk/government/consultations/regulating-healthcare-professionals-protecting-the-public). This noted that regulators will still need to consider the context – including the time that has elapsed since a concern was raised – when deciding whether to pursue fitness to practise against a registered healthcare professional. We will set out more detail on the timing of delivering these changes when we publish the government response to this consultation in the coming months.
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.	Government accepted this action in principle. Our 2021 response (https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-government-response) outlined our approach to implementing this action for improvement. The new Patient Safety Commissioner will work closely with regulatory bodies to promote the patient voice and improve patient safety in the context of medicines and medical devices.
Organisations who take complaints from	Government accepted this action in principle. Our 2021 response

Action for improvement	Progress
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.	(https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-government-response) outlines our approach to implementing this action for improvement.

3. Redress

Claims gateways

Recommendation 3 of the review 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. The government has no plans to establish an independent redress agency.

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.

Progress update

On 15 June, NHS Resolution launched 2 claims gateways on their website to provide further support to patients who may wish to bring a clinical negligence claim in relation to pelvic mesh and sodium valproate.

While the government is sympathetic to those affected by the review, our priority remains on making medicines and devices safer through a wide range of activities.

We have worked with NHS Resolution (NHSR) to launch 2 claims gateways on their website to provide further support to patients who may wish to bring a clinical negligence claim in relation to pelvic mesh and sodium valproate. These are:

- pelvic mesh claims gateway (https://resolution.nhs.uk/vaginal-mesh/)
- sodium valproate claims gateway (https://resolution.nhs.uk/sodium-valproate/)

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

The gateways contain a range of materials, including:

- factual information for patients affected by mesh and sodium valproate on how to bring a claim against an NHS trust or provider
- 2 bespoke routes for providing the details of their claim that NHSR can use to initiate an investigation – a letter of claim template or a questionnaire
- a form for the disclosure of medical records
- sources of independent legal advice
- a dedicated mailbox at NHSR where completed documents can be sent

While the gateways make the process to initiate a claim easier for claimants, they do not represent a change to the existing legal framework – claims will continue to be assessed against the normal legal threshold for clinical negligence.

Actions for improvement

Action for improvement	Progress
There is a need for additional training for those carrying out assessments for the Department	Government accepted this action for sodium valproate and vaginal mesh. Our 2021 response outlines our approach to implementing this recommendation.

Action for improvement	Progress
for Work and Pensions (DWP) based on the insight condition reports. This should help those carrying out the assessments to make equitable decisions.	Shaping future support: the health and disability green paper (https://www.gov.uk/government/consultations/shaping-future-support-the-health-and-disability-green-paper), published in 2021, explored how the benefits system can better meet the needs of claimants now and in the future by improving claimant experience of our services, enabling independent living and improving employment outcomes. The DWP received over 4,500 responses to the public consultation, which ran from July to October 2021, and will respond to the green paper with a white paper in due course.

4. Pelvic mesh

This section updates on the work of the first part of recommendation 5 – specialist mesh services, as well as wider work on pelvic mesh.

Specialist mesh services

The first part of recommendation 5 states:

> “ Networks of specialist centres should be set up to provide comprehensive treatment, care and advice for those affected by implanted mesh.”

Government response

We accept this recommendation. NHSE 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.

Progress update

Complete. There are now 9 centres for patients with complications of mesh inserted for urinary incontinence and vaginal prolapse (specialist mesh centres) in operation in England, which ensures that women in every region have access to these services.

At the time of publication of the government response, 8 specialist mesh centres had been established with progress being made to establish a ninth centre in

the south west. On 27 April 2021, we announced that North Bristol NHS Foundation Trust had been selected to provide these specialised services (https://www.nbt.nhs.uk/our-services/a-z-services/mesh-complications-specialist-service) and, as of 1 April 2022, this centre became operational.

This ensures that all women who have been affected by pelvic mesh can access the support they need, wherever they live in England. Between April 2021 and October 2022:

- 1,913 patients have been referred for treatment
- 393 patients have received surgery
- 192 are on the surgical waiting list
- 136 patients opted for non-surgical treatment

The average waiting time for a first outpatient appointment in this time period was 15 weeks. The average waiting time for surgery in this time period was 23 weeks.

When seeking treatment at the specialist mesh centres, patients have access to professionals from a range of clinical disciplines. Each mesh centre, as required by the service specification, is led by a multidisciplinary team to ensure patients get access to the specialist care and treatment that they need, including pain management and psychological support.

Before treatment takes place, each patient's case must be discussed by their multidisciplinary team. Membership of the mesh centre multidisciplinary team is as follows.

Core membership of the multidisciplinary team is:

- a named consultant sub-specialist in urogynaecology
- a named consultant urologist with expertise in female urological conditions
- a 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)

Other optional membership of the multidisciplinary team is:

- a 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

- a neurosurgeon

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. All urologists forming part of the specialist multidisciplinary team must have membership of the female, neurological and urodynamic urology section of the British Association of Urological Surgeons.

To further equip doctors with the necessary clinical skills to treat patients with complications from implanted mesh, the Royal College of Obstetricians and Gynaecologists (RCOG), in collaboration with partners including the Royal College of Surgeons, has developed a Mesh Complications Management Training Pathway (https://www.rcog.org.uk/careers-and-training/training/curriculum/mesh-complications-management-training-pathway/). Patients with personal experience of mesh complications also provided input to the development of this pathway.

The pathway's curriculum will consist of 4 capabilities to practise, outlined below.

1. The doctor has the knowledge, skills and attitudes required for clinical assessment of patients presenting with suspected mesh-implant complications.
2. The doctor is able to investigate mesh complications and interpret the results of tests appropriately.
3. The doctor is competent in non-surgical management of mesh complications.
4. The doctor is competent to undertake mesh removal surgery as part of a multidisciplinary team.

RCOG and partners aim to launch the pathway in spring 2023.

In the future, they aim to have it approved as a GMC credential, subject to the success of the GMC's pilot of 5 early adopter credentials in other areas of medicine. Following the outcome of these pilots, the GMC will consider the pathway in 2023.

All specialist mesh centres must meet at an annual clinical summit to promote best practice, present data and share patient outcomes. The first summit took place on 6 December 2022 where all 9 mesh centres came together to share best practice in:

- setting up the centres
- delivering patient-centred care
- ensuring robust data collection to support continued improvement

Shared decision-making and patient consent are paramount within the specialist mesh centres. Before treatment takes place, including surgical and non-surgical treatment, patients are informed of the options available to them and the risks that may arise. To facilitate patient-informed choice, NHSE and NICE have developed patient decision aids.

NHSE carried out interviews in September and October 2022 with patients who have been treated by the mesh centres to receive feedback about their experience of the service and the treatment received.

As part of the treatment-planning and patient decision-making process, patients who have concerns around receiving treatment from a surgeon who originally carried out their mesh implantation can discuss this with their multidisciplinary team, exercise choice and be referred to another specialist mesh centre if that is what they want.

NHSE has also worked with NHS Health Education England and eLearning for Healthcare to develop a training programme on pelvic mesh complications for GPs (https://www.e-lfh.org.uk/programmes/pelvic-mesh-complications/). This will support GPs to understand the symptoms of mesh complications and the services available, ensuring that women are assessed and referred to a specialist mesh centre.

Next steps

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

The 9 specialist mesh centres do not currently offer treatment for patients who have been adversely affected by rectopexy mesh – that is mesh inserted into the rectum to treat prolapse and other rectal complications.

NHSE is amending the specialised service specification for women with complication of mesh inserted for urinary incontinence and vaginal prolapse to include treatment for patients – both female and male – with a range of rectopexy complications, which include rectal prolapse and obstructive defaecation. NHSE has considered stakeholder views on the updated service specification (https://www.england.nhs.uk/publication/specialised-services-for-women-with-complications-of-mesh-inserted-for-urinary-incontinence-and-vaginal-prolapse-16-years-and-above/).

Services will be commissioned from within the specialist mesh centres to provide rectopexy services in early 2023. Where patients considering rectopexy mesh management are to be treated, specialist mesh multidisciplinary team membership will be expanded to include relevant experts.

Enhanced data collection – the Pelvic Floor Information System

The review recognised the need for better data collection and the 2021 response acknowledged this. NHSE is working to ensure high-quality data is collected within the specialist mesh centres.

A patient questionnaire has been designed, which includes both patient-reported outcome measures (PROMs) and patient-reported experience

measures (PREMs). This questionnaire incorporates the existing pelvic floor PROMs that are in use by clinicians, as well as additional questions that have been requested by clinicians who are treating patients with complications of mesh insertion.

This patient questionnaire serves as a temporary solution, pending the development of a validated PROM for pelvic floor disorders, which is being commissioned by the National Institute for Health and Care Research (https://www.nihr.ac.uk/documents/21583-patient-reported-outcome-measures-proms-for-pelvic-floor-disorders-commissioning-brief/29590) and is subject to receiving high-quality bids.

Development, testing, evaluation and validation of a new PROM can take 2 to 3 years and requires patient, clinical and specialist academic input to ensure that the data collected is suitable for outcome-based analysis and evaluation.

As part of the Pelvic Floor Information System, we have established a Pelvic Floor Registry. The Pelvic Floor Registry is a database that collects surgical device and implant data directly from NHS and private healthcare providers in the UK, with a focus on pelvic floor procedures including the use of surgical mesh and comparable treatments.

The data collected from the patient questionnaire within the specialist mesh centres, described above, will begin feeding into the Pelvic Floor Registry in May 2023.

The review also recommended that the development of the Pelvic Floor 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.”

We accepted this recommendation, and NHS Digital has undertaken work to complete an audit of all pelvic floor surgery completed in 2010 to generate a historical baseline of outcomes by procedure type, and to support further research and analysis. This audit was conducted using Hospital Episode Statistics data (https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/hospital-episode-statistics), in addition to other nationally collected data using the identified NHS cohort of patients and the longitudinal record to observe outcomes over time where possible. The audit has been completed and is undergoing peer review prior to publication in 2023.

The high vigilance restriction on the use of mesh

As set out in our 2021 response, a ‘high vigilance restriction’ – also referred to as a ‘pause’ – is in place on vaginally inserted mesh to treat prolapse, and on the use of tape or slings to treat stress urinary incontinence (SUI).

The high vigilance restriction has a number of conditions, which were set by NHSE to ensure a consistent and high-quality service. These conditions include:

- comprehensive data collection
- setting up a Pelvic Floor Registry
- ensuring that doctors implanting pelvic mesh have the experience and appropriate training to do so

NHSE continues to monitor progress against the pause conditions. Once sufficient progress has been met on these conditions, and in discussion with the Pelvic Floor Health Oversight Group, we will consider changes to pause restrictions.

Strategic leadership – the Pelvic Floor Health Oversight Group

The Pelvic Floor Health Oversight Group – whose membership comprises both patients and clinicians – has been undertaking work to implement this pelvic mesh-related recommendation and the actions for improvement as part of its programme of work.

Since publication of the 2021 response, NHSE has established 2 further subgroups to complement the workstreams that were already in place.

NHSE has also been developing the Pelvic Floor Registry with NHS Digital, working to improve care for women experiencing stress-urinary incontinence and pelvic organ prolapse, and promote education and training in pelvic floor health.

Actions for improvement

Pelvic mesh

The report contains 15 actions for improvement related to pelvic mesh, set out below:

Action for improvement	Progress
Further research is urgently needed so that a clearer view can be reached on the inherent properties and	Government accepted this action in principle. Last year, the National Institute for Health Research (NIHR) commissioned a £500,000 study on women's experiences of urogynaecology health services in the UK (https://fundingawards.nihr.ac.uk/award/NIHR202450). The study will be completed in early 2023, and its findings

Action for improvement	Progress
safety of pelvic mesh.	will be used to support patients, inform healthcare professionals and help shape health services. We expect that it will also be used to inform the development of a validated PROM for pelvic floor disorders, as described above. The NIHR continues to welcome funding applications for research into any aspect of human health, including the safety of pelvic mesh.
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 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.	Government accepted this action in principle. The government response to the public consultation on the future UK medical device regime, described in section 7, outlines the government's intention to introduce more stringent post-market surveillance requirements. This will ensure that manufacturers are required to implement a post-market surveillance system based on a post-market surveillance plan for all medical devices placed on the UK market. The plan will collate and utilise information gathered from various sources such as serious incident data, relevant literature, and patient and public involvement. This will outline the mechanisms that manufactures take to address serious adverse incidents. The government also intends to publish guidance to further clarify the requirements of post-market surveillance plans.
We recommend that, when a device or procedure is introduced, a cohort of early recipients undergo enhanced reporting to detect unexpected adverse impacts.	Government accepted this action in principle. To help improve the quality of data to support medical device use, the consultation on future UK medical device regime (described in section 7 below) also included proposals to introduce more stringent requirements relating to clinical investigations, and performance studies of general medical devices and in vitro diagnostic (IVD) devices respectively. By introducing these more stringent requirements, this will

Action for improvement	Progress
	help to reduce the risks of unexpected adverse impacts once the device is placed onto the market.
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.	Government accepted this action. NICE carried out an exceptional review of NICE guidance [NG123] urinary incontinence and pelvic organ prolapse in women: management (https://www.nice.org.uk/guidance/ng123) in 2021. This review did not identify any new evidence that would justify an update to the current guidance. The NICE guidance states that a transobturator approach should not be offered unless there are specific clinical circumstances and gives an example of an 'exceptional circumstance'. It is therefore considered that the recommendation is in line with this action for improvement. NICE will continue to actively monitor and use its established guidance surveillance processes to assess any arising new evidence, and consider an update to the guidance, if appropriate, based on this evidence.
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.	Government accepted this action. As set out in the 2021 response, the BSUG has established a mentorship scheme, approved by the Specialty Education Advisory Committee of the RCOG. It ensures that any consultant clinician undertaking a stress urinary incontinence procedure has adequate training to complete this. Between the scheme opening for registration in 2019 and November 2022, 42 clinicians have registered for the mentorship scheme and 18 have completed it. All urology trainees are required to demonstrate competency regarding the management of patients with stress urinary incontinence, as included in the advanced curriculum in urology. For sub-specialist functional urologists, a level 4 competency is required (able and trusted to act at the level of a day one consultant) and, for general urologists with a specialist interest in female urology, a level 3 competency is required (able and trusted to act with indirect supervision). These

Action for improvement	Progress
	requirements ensure new consultants are appropriately trained in this subspecialty. To equip doctors with the necessary clinical skills to treat patients with complications from implanted mesh, the RCOG, in collaboration with partners including the Royal College of Surgeons, has developed a Mesh Complications Management Training Pathway (https://www.rcog.org.uk/careers-and-training/training/curriculum/mesh-complications-management-training-pathway/). RCOG aims for this to be launched in spring 2023 and approved as a GMC credential later in 2023. The British Association of Urological Surgeons (BAUS) has partnered with the National Consultant Information Programme to collate data pertaining to consultant outcomes, length of stay, readmission rates and surgeon volume, and plot these metrics relevant to peers. Five procedures pertaining to urinary incontinence are currently active on this platform and urology has been a specialty in this initiative. Going forward, the Pelvic Floor Registry set up by NHS Digital will be expected to capture this data. Data regarding surgical outcomes is a key part of the appraisal process and summaries have been used routinely by members for this purpose.
A culture must exist where all multidisciplinary team members feel able to speak up and that their input will be listened to. Trusts must work to create a culture that facilitates effective multidisciplinary teams.	Government accepted this action. In line with the service specification, each of the specialist mesh centres has a multidisciplinary team in place to support the delivery of treatment for patients with complications of mesh inserted for urinary incontinence and vaginal prolapse. All multidisciplinary team meetings include professional input from a range of specialties. See the section on ‘Specialist mesh services’ above for further detail on the clinical membership of the multidisciplinary teams. Mesh centre multidisciplinary team meetings are organised a year in advance and minutes are recorded for all meetings. All specialist mesh centres have confirmed their understanding of the importance of

Action for improvement	Progress
	effective multidisciplinary team working, and recognise that the multidisciplinary team can only function if all members play an active part and contribute towards treatment planning. Feedback from all of the specialist mesh centres' multidisciplinary team members (both core and extended members) has highlighted that they are all inclusive and effective. Furthermore, all multidisciplinary team members have completed trust-wide mandatory training in equality and diversity. Furthermore, as set out in the government response to the Paterson inquiry (https://www.gov.uk/government/publications/government-response-to-the-independent-inquiry-report-into-the-issues-raised-by-former-surgeon-ian-paterson), as part of the CQC's health assessment framework under the 'effective' key line of enquiry, providers are asked: 'How well do staff, teams and services within and across organisations work together to deliver effective care and treatment?', as well as specific questions on multidisciplinary working across all services. The CQC is also developing an updated regulatory model in line with its new organisational strategy from 2021. As part of this, it will ensure that the assessment of compliance with up-to-date national guidance on multidisciplinary teams continues to be a focus for the NHS and the independent sector.
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,	Government accepted this action. The NHS Long-Term Plan (https://www.longtermplan.nhs.uk/) commits to improving access to postnatal physiotherapy and for all women to have access to multidisciplinary pelvic healthcare across England by March 2024. This will be delivered locally through the establishment of perinatal pelvic health services. Following the successful rollout by early implementer local maternity systems, NHSE will continue to roll out perinatal pelvic health services, which will be established in at least two-thirds of all local maternity systems by March 2023, with a view to all women in England having access to the services by the end of

Action for improvement	Progress
professional organisations and Royal Colleges. A co-ordinated strategy can then be developed to remedy the gap.	March 2024. Perinatal pelvic health services are expected to have many benefits, which include: – improved prevention and identification of mild to moderate pelvic floor dysfunction around birth – timely access to NICE-recommended treatment for common pelvic health issues antenatally – postnatally, fewer women living with long-term pelvic floor dysfunction in England, reducing the associated personal, societal and financial costs – improvement in women's experiences of perinatal pelvic healthcare Patients that are considering treatment for mesh-related complications at any of the specialist mesh centres are always provided with the opportunity to discuss their cases with mesh multidisciplinary team members. All of the mesh centres have direct access to physiotherapy support and physiotherapy staff are included in the multidisciplinary team. Patient decision aids have been developed to support shared decision-making between the patient and their multidisciplinary team. This ensures that patients are informed of all available treatment options, including conservative and non-surgical measures, and the possible risks and benefits of these treatment options, so they can make an informed choice. National groups for a variety of healthcare professions have been set up by clinical members of the specialist mesh centres' multidisciplinary teams. These groups provide specialist mesh centre physiotherapists with the opportunity to share and develop best practice and, ultimately, improve patient care.
Clinicians must ensure patients have sufficient understanding of their treatment including the benefits, the potential risks it	Government accepted this action. Patients that are considering treatment for mesh-related complications are always provided with the opportunity to discuss their cases with the specialist mesh centres' multidisciplinary team members. Furthermore, patients also have access to patient information leaflets that detail treatment options, risk and benefits.

Action for improvement	Progress
presents and the alternative treatment options, including doing nothing, in order to decide whether they are willing to have that treatment.	Patient decision aids (https://www.nice.org.uk/guidance/ng123/resources/patient-decision-aids-and-user-guides-6725286109) have also been developed for the specialist mesh centres to support shared decision-making between patients and their multidisciplinary team. This ensures patients are fully informed of the treatment choices, including conservative and non-surgical measures, and the possible risks and benefits of all treatment options, enabling them to make informed choices.
Clinicians need to establish and agree terminology and definitions related to both mesh insertions and removals.	Government accepted this action. Patient decision aids (https://www.nice.org.uk/guidance/ng123/resources/patient-decision-aids-and-user-guides-6725286109) 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 the 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.
An audit to establish complication rates should be attempted using the women who had mesh insertions in 2010.	Government accepted this action. NHS Digital has undertaken work to complete an audit of all pelvic floor surgery completed in 2010 to generate a historical baseline of outcomes by procedure type, and to support further research and analysis. This audit was conducted using Hospital Episode Statistics data (https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/hospital-episode-statistics) in addition to other nationally collected data using the identified NHS cohort of patients and the longitudinal record to observe outcomes over time where possible. The audit has been completed and is undergoing peer review prior to publication in 2023.

Action for improvement	Progress
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 monitors the situation and update its guidance promptly once a consensus has been reached.	Government accepted this action. 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. NICE has undertaken an exceptional review into guidance [NG123] urinary incontinence and pelvic organ prolapse in women: management (https://www.nice.org.uk/guidance/ng123), which did not identify any new evidence to justify updating the guidance. Regarding treatment at the specialist mesh centres, the service specification 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, in addition to the risks attached to each procedure. It is paramount that all potential outcomes must be discussed in advance as, even when a full removal is planned, this may not always be feasible due to complications revealed during the operation.
Consideration should be given to credentialing a small number of centres and surgeons for particularly complex pelvic mesh surgeries.	Government accepted this action. The RCOG is leading on the development of a credential with the support of partners and specialist societies. These partners include the: – Royal College of Surgeons (Royal College of Surgeons of England, Royal College of Surgeons of Edinburgh, and Royal College of Physicians and Surgeons of Glasgow) – BSUG – BAUS section of female, functional, neuro-urology and urodynamics – Association of Coloproctology of Great Britain and Northern Ireland

Action for improvement	Progress
	– Pelvic Floor Society For details of what the curriculum will cover, see ‘Specialist mesh services’ above.
A remote counselling service along the lines we set up during this review should continue to exist.	Government did not accept this action. The 2021 response set out our rationale.
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 postnatal pelvic floor rehabilitation.	Government accepted this action in principle. As set out in our update on the action ‘Conservative measures must be offered to women before surgery’, NHSE is rolling out perinatal pelvic health services across England. As set out in our 2021 response, 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 the menopause. NHS England is working with the PSHE Association to develop a lesson plan for pelvic floor health, which should be launched at the beginning of 2023.
Dismissive, defensive attitudes by surgeons are a cultural issue that needs to be addressed by the medical profession, its professional bodies and regulators.	Government accepted this action. The GMC is currently reviewing its core ethical guidance for the medical profession, Good medical practice (https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice). This 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 its engagement with registrants and patients. The GMC has invited views from stakeholders (https://www.gmc-uk.org/ethical-guidance/good-medical-practice-review/take-part-in-the-good-medical-practice-consultation), including the organisation’s patients and healthcare professionals,

Action for improvement	Progress
	which will feed into the review. In 2021, the GMC completed its review of all postgraduate curricula. With the exception of cytopathology, the GMC has now approved all postgraduate Certificate of Completion of Training and subspecialty curricula against its standards of 'excellence by design'. This means that the curricula will incorporate the generic professional capabilities framework (https://www.gmc-uk.org/education/standards-guidance-and-curricula/standards-and-outcomes/generic-professional-capabilities-framework), which includes a section on the personal and professional values and behaviours that are expected of doctors. As set out in our 2021 response, the BAUS and BSUG continue to provide information and training to their members on both patient consent and mesh issues.

5. Improving the safety of medicines taken during pregnancy

Improving pathways of care

The second part of recommendation 5 states:

> " Networks of specialist centres should be set up to provide comprehensive treatment, care and advice…for those adversely affected by medications taken during pregnancy."

Government response

We do not accept this recommendation.

However, we recognise the underlying issue that there is a need to improve care and support for the individuals and families affected by a range of medicines used in pregnancy, including sodium valproate exposure.

Our view was that a network of new specialist centres is not the most effective way forward. We will 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 ensure that sodium valproate is only prescribed

where clinically appropriate.

Progress update

We have taken forward work to improve care pathways for children and families adversely affected by other medicines in pregnancy.

In our 2021 response, we recognised the need to:

- improve care pathways for children and families affected by medicines in pregnancy
- reduce variations 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

NHSE has since undertaken work to scope options to improve care pathways. As part of this work, NHS England commissioned the Paediatric Neurosciences Clinical Reference Group (https://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-e/e04/) to support the development of a model pathway that could be used and tailored locally to enable multi-agency working. The Paediatric Neuroscience Clinical Reference Group established and brought together a Teratogen Clinical Development Group, chaired by Dr Charlie Fairhurst (consultant in paediatric neurodisability).

The Teratogen Clinical Development Group has recommended a proposal for regional multidisciplinary and interdisciplinary 'hub and spoke' services to sit within specialised neurodisability teams (providing the hub element). These services will support the identification, assessment and diagnosis of high-risk infants, children and young people exposed to teratogens.

NHSE will explore this recommendation further with relevant integrated care boards, as they are assuming responsibility for specialised services, including neuroscience and neurodisability services.

Improving the safety of medicines in pregnancy

The MHRA has continued to deliver its programme of work to improve the safety of medicines taken during pregnancy. 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.

The MHRA is 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.

In January 2021, the MHRA published its strategy for its Safer Medicines in Pregnancy and Breastfeeding Consortium (https://www.gov.uk/government/publications/safer-medicines-in-pregnancy-and-breastfeeding-consortium). 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 consortium meets 3 to 4 times a year, and it has added insight and value on a range of topics including enhancing the quality and consistency of information on the use of medicines in pregnancy and breastfeeding, including coronavirus (COVID-19) vaccines.

The MHRA is also engaging with other organisations to support implementation of the recommendations of the Expert Working Group on Optimising Data on Medicines used During Pregnancy (https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-optimising-data-on-medicines-used-during-pregnancy). This expert working group published recommendations on how to ensure the UK makes better use of real-world data on medicines exposure during pregnancy and breastfeeding. Recent progress includes NICE updating its guideline [NG201] antenatal care (https://www.nice.org.uk/guidance/ng201) to improve medication data captured during pregnancy, which will ensure better maternal care for women and better data for research on the safety of medicines in pregnancy.

The MHRA has now completed the first stage of its work to support better evidence-based dosing for medicines used in pregnancy and in related training for obstetricians. This work secured funding from the Bill and Melinda Gates Foundation for a 2-year project. Improving this evidence will help ensure more is known about optimal efficacy and minimal toxicity of medicines, and will give obstetricians further clarity on the optimal dose of a medicine when treating pregnant patients.

After successful completion of the first stage of this project, further funding from the Bill and Melinda Gates Foundation has been awarded to fund work until March 2025. Several publications are in preparation and there will be a new online portal to publish these, as well as any new evidence produced going forward. The MHRA has run training in January 2022 and again in October 2022 for academic clinicians interested in studying medicines used during pregnancy and clinicians (for example, obstetricians, obstetric physicians and other specialists) who treat women needing to take medication during pregnancy.

The UK is carefully considering regulatory approaches for handling the risks of teratogenic medicines. To ensure these remain up to date, the MHRA is conducting a review of its current processes and guidance to establish if any elements can be strengthened. The first stage of this review is scheduled to complete in the current financial year. The findings will be subject to independent patient and stakeholder input and expert advice, and, if needed, follow-up action and updated guidance will be carried out next year.

Understanding how diseases, medicines and vaccines, and other exposures affect the health of pregnant women and their children is an important public health priority. The MHRA has also now expanded the Clinical Practice Research Datalink Pregnancy Register (an algorithmic pregnancy register based on electronic healthcare records) to include anonymised data on 24.5

million pregnancy episodes across 10 million women, greatly increasing its ability to study rare exposures and outcomes, and thus improving healthcare advice to women.

The expanded Clinical Practice Research Datalink Pregnancy Register is being used by the MHRA to study the safety of COVID-19 vaccination during pregnancy and in another study to improve the understanding of dose-exposure-response relationship of hormonal contraceptives.

6. Sodium valproate

We are continuing to take forward work to ensure sodium valproate is only used where clinically appropriate. We also continue to improve patient safety for women and girls able to have children for whom there is no alternative medicine by ensuring that a pregnancy prevention programme (PPP) is in place with annual reviews.

NHSE and the MHRA have a programme of work in place that covers a broad range of areas. This includes:

- reducing prescribing and seeking safer alternatives to sodium valproate
- pregnancy prevention and contraception for women and girls taking valproate who are able to have children
- ensuring patients' decisions are based on informed consent and shared decision-making with their doctors
- improving the data collection so that we can monitor the effectiveness of this work and identify issues

Stronger risk minimisation prescribing measures

The MHRA continues to evaluate the risks and benefits associated with any medicine, including sodium valproate. The safety of sodium valproate was discussed at several Commission on Human Medicines (https://www.gov.uk/government/organisations/commission-on-human-medicines) (CHM) meetings between May and August 2022 where they reassessed the most appropriate regulatory measures to best minimise risks associated with sodium valproate.

CHM's consideration was informed by 2 meetings involving stakeholder engagement with experts and those with personal experience of the medicine, many of whom are members of the MHRA's Valproate Stakeholder Network, and actively involved in the implementation of the existing risk minimisation measures and evaluation of their effectiveness.

The MHRA is introducing stronger risk minimisation measures to continue to reduce the number of pregnancies exposed to sodium valproate, including the recommendation for no new patients under 55 years of age to be prescribed

sodium valproate unless 2 specialists independently consider and document that no other medicine is effective or tolerated.

For patients already receiving sodium valproate, 2 specialists will need to independently consider and document that no other medicine is effective or tolerated and that the patient should continue to receive sodium valproate.

These restrictions follow a robust review of scientific evidence. A dedicated group has been convened by the CHM to advise on the safe implementation of the new measures, which includes a phased approach.

Updated National Institute for Health and Care Excellence guidance

In April 2022, the National Institute for Health and Care Excellence (NICE) published a new guidance [NG217] Epilepsies in children, young people and adults (https://www.nice.org.uk/guidance/ng217). This updated and replaced the previous guidance [CG137] Epilepsies: diagnosis and management (https://www.nice.org.uk/guidance/cg137), which was published in January 2012.

This NICE guidance is clear that sodium valproate should not be offered to women and girls able to have children, including young girls who are likely to need treatment when they are old enough to have children, unless:

- other options are unsuccessful
- the risks and benefits have been fully discussed
- a PPP is in place

Furthermore, NICE no longer recommends sodium valproate as a first-line treatment for focal epilepsy, and may only be used if other medicines, such as carbamazepine or lamotrigine, are not effective.

NICE's recommendations on sodium valproate will need to be updated again to reflect the strengthened regulatory position being introduced by the MHRA.

Pregnancy prevention and contraception

Pregnancy prevention programme

The pregnancy prevention programme (PPP) is designed to ensure that female patients who are able to have children are fully aware of the risks associated with taking sodium valproate during pregnancy and the need to avoid becoming pregnant while taking the medication.

Conditions of the programme include:

- at least annual treatment reviews by a specialist
- a signed risk acknowledgement form at each review

- the use of highly effective contraception for people for whom pregnancy is a possibility

To ensure that prescribers and patients always have access to the risk acknowledgement form, a digital version is needed. Currently, the form is available as a PDF that can be edited and uploaded to patient notes, and MHRA and NHS Digital are developing a prototype digital version of the form.

Valproate Safety Implementation Group

NHSE has taken forward a programme of work through its Valproate Safety Implementation Group (https://www.england.nhs.uk/patient-safety/sodium-valproate) (VSIG), led by the NHSE National Director for Patient Safety, to reduce harm caused by sodium valproate. This includes:

- looking at improved patient information
- support for de-prescribing
- pregnancy prevention

For example, VSIG is looking at the best way that the PPP can ensure that highly effective contraception is provided, and educate both patients and healthcare workers about the risks of pregnancy while taking this medication.

Improving data collection

Medicines and Pregnancy Registry

To support the strengthened regulatory measures, the MHRA and NHS Digital established a Valproate Registry now known as the Medicines and Pregnancy Registry (https://digital.nhs.uk/data-and-information/publications/statistical/mi-medicines-and-pregnancy-registry) (the registry). The registry contains data on all NHS prescriptions of valproate in girls and women of childbearing age in England dispensed in the community, and identifies if they are pregnant and accessing NHS care for that pregnancy.

Through the registry, the MHRA monitors the effectiveness of the PPP, and can understand changes in the use of sodium valproate over time and the impact of these changes on women and their children. In line with the commitment made in the 2021 government response, the MHRA and NHS Digital have expanded the registry to include other anti-epileptic drugs taken during pregnancy.

The first report from the registry was published in February 2021. The latest available data was published in September 2022, capturing data from April 2018 to March 2022 (https://digital.nhs.uk/data-and-information/publications/statistical/mi-medicines-and-pregnancy-registry/antiepileptic-use-in-females-aged-0-to-54-in-england-april-2018-to-march-2022), and covers other anti-epileptic drugs in addition to sodium valproate.

This showed that, since 2018, there has been an approximately 75% drop in prescribing during pregnancy, and an almost 30% drop in prescribing to girls and women under 54 years of age. The registry suggests that, in the last 6-monthly reporting period (October 2021 to March 2022), 17 women were prescribed valproate during pregnancy and appear to have started valproate during pregnancy. Identification of these exposures through the registry has enabled more detailed follow-up to further understand challenges with the implementation of the PPP in practice.

It should be noted this registry covers England and that, as the registry is based on routine data collections, there will be some missing information.

Valproate Safety Dashboard

In conjunction with the NHS Business Services Authority, the implementation group has developed a set of prescribing indicators to track the use of sodium valproate medicines among women of childbearing potential. The valproate safety dashboard (https://www.nhsbsa.nhs.uk/epact2/dashboards-and-specifications/valproate-safety-dashboard) (the dashboard) has been created to monitor sodium valproate use in a way that is straightforward for patients, the public and health professionals.

The data collected from the dashboard is used to:

- analyse prescribing patterns
- support a reduction in the use of valproate in women of childbearing potential
- help prevent unplanned pregnancies in women taking valproate

Patient information and shared decision-making

Whole pack dispensing of medicines containing sodium valproate

We have listened to the concerns of women who are dispensed a prescription for medicines containing sodium valproate in white boxes without the patient information leaflet inside.

In November 2021, DHSC, in partnership with the MHRA, launched a 6-week consultation on original pack dispensing and whole pack dispensing of medicines containing sodium valproate (https://www.gov.uk/government/consultations/original-pack-dispensing-and-supply-of-medicines-containing-sodium-valproate). This included a proposal to amend the Human Medicines Regulations 2012 (https://www.legislation.gov.uk/uksi/2012/1916/contents/made) with a specific requirement that medicines containing sodium valproate are always dispensed in the original manufacturer's packaging. This will ensure patients, and particularly women and girls of childbearing potential, always receive the patient information leaflet with warnings about taking the medicine while pregnant.

The government has considered the responses received and will shortly publish a response to the consultation with a decision about the proposed amendment to the Human Medicines Regulations 2012.

Patient decision aids

To ensure that all women are aware of the risks attached to sodium valproate and encourage shared decision-making, the VSIG is developing 2 patient decision aids. These patient decision aids are: 'Bipolar disorder: is valproate the right treatment for me?' and 'Is valproate the right epilepsy treatment for me?'. They will be available online, and in both primary and secondary care settings.

Community pharmacy NHS New Medicine Service

From 1 September 2021, epilepsy medication was included in the New Medicine Service (https://www.england.nhs.uk/publication/advanced-service-specification-nhs-new-medicine-service-nms/) as part of the community pharmacy contractual framework.

This service is provided by over 90% of community pharmacies to support patients of all ages with newly prescribed medicines and provide follow-up consultations in the first months of taking a new medicine.

Pharmacist requirements

MHRA guidance states that pharmacists should always provide the statutory patient information leaflet to female patients with a valproate medicine, even when dispensed in a pharmacy 'white dispensing box' (plain carton). They should:

- remind women of the risks and provide a patient card every time they are dispensed a valproate medicine – as situations can change and a one-time conversation is not sufficient
- check whether women are enrolled in the PPP and have signed a risk acknowledgement form – if not, they should dispense the prescription and advise the patient to speak to her GP as soon as possible (including by contacting the GP directly if necessary) for a specialist referral

2022 to 2023 community pharmacy contractual framework national clinical audit

NHSE and the Pharmaceutical Services Negotiating Committee have agreed that, in 2022 to 2023, all community pharmacy contractors will carry out a national clinical audit on preventing harm from valproate prescribing in female patients of childbearing age (https://www.england.nhs.uk/long-read/2022-23-community-pharmacy-contractual-framework-national-clinical-audit/). This follows the publication of the recommendations of the previous audit carried out in 2019 to 2020 (https://www.england.nhs.uk/publication/community-pharmacy-preventing-harm-from-valproate-pharmacy-quality-scheme-audit-report-2019-20/).

The aims of the audit are to:

- reduce the potential for harm from valproate prescribing in patients of childbearing age who are biologically able to be pregnant
- reinforce the actions that the MHRA has advised pharmacists need to undertake when dispensing valproate to patients of childbearing age who are biologically able to be pregnant
- assess the extent to which the recommendations of the 2019 to 2020 valproate audit have been embedded into practice

The audit will check what percentage of patients:

- are provided with a patient card by the pharmacy every time valproate is dispensed
- have received the patient guide
- are referred or signposted to their GP practice or specialist if they:
  - have not received a review from a specialist in the last 12 months
  - are not on highly effective contraception in line with the PPP

The audit should be completed no later than 31 March 2023.

Actions for improvement

Action for improvement	Progress
An indicator on safe prescribing in pregnancy should be introduced for future iterations of the Quality and Outcomes Framework (https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/general-practice-data-hub/quality-outcomes-framework-qof).	Government did not accept this action. The 2021 response set out our rationale.
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.	Government accepted this action. The NHSE VSIG (https://www.england.nhs.uk/patient-safety/sodium-valproate) is working to reduce the use of sodium valproate in women of childbearing potential. The group has supported implementation of the PPP, which includes access to appropriate contraception and sexual and reproductive health advice.

Action for improvement	Progress
	The group is also working to improve information provision for women of childbearing potential and healthcare workers about the risks of pregnancy while taking this medication. NHSE wrote to all women of childbearing potential who are prescribed sodium valproate to provide information on the risks of pregnancy. The group is also working with the Association of British Neurologists to develop guidance on safely de-prescribing sodium valproate in women of childbearing potential. These risks include sudden unexplained death in epilepsy, relapse and self-harm. The VSIG recommended the development of a national shared care protocol for sodium valproate, as there has been some confusion among prescribers and clinicians regarding responsibilities for monitoring those who use sodium valproate. This has been developed and prioritised in the national care protocol system. Shared care protocols enable GPs to prescribe and monitor medicines or treatments in primary care in agreement with the initiating specialist.
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.	Government is considering this action. Our 2021 response outlines our approach to this action for improvement.
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 children collated over	Government accepted this action. The Valproate registry – now called the Medicines and Pregnancy Registry (https://digital.nhs.uk/data-and-information/publications/statistical/mi-medicines-and-pregnancy-registry) – has now been expanded to include other anti-epileptic drugs taken during

Action for improvement	Progress
lifetimes. This registry could potentially be expanded to collect data on paternal and transgenerational effects.	pregnancy and used to follow up on recent potentially exposed pregnancies. View the latest report of the registry (https://digital.nhs.uk/data-and-information/publications/statistical/mi-medicines-and-pregnancy-registry/antiepileptic-use-in-females-aged-0-to-54-in-england-april-2018-to-march-2022), which was published in September 2022. The MHRA is working with NHS Digital to gain further insight from the registry on exposed pregnancy outcomes and unintended consequences of switching treatment. It is also exploring with NHS Digital how a digital annual risk acknowledgment form to fully monitor adherence to the PPP could be implemented and integrated with the register.
The relevant stakeholders should continue to work with patient groups to monitor and improve the PPP and to consider the next steps, which should include NHSE writing directly to all women and girls of childbearing potential asking them to see their general practitioner or specialist.	Government accepted this action. On 14 June 2021, NHSE sent a letter to all women and girls of childbearing age prescribed valproate in England (https://www.england.nhs.uk/publication/letter-to-women-and-girls-taking-sodium-valproate/) to ask them to see their general practitioner or a specialist on an annual basis. The VSIG is working with patient and public voice representatives and the Winton Centre to develop additional resources for patients, including risk communication and shared decision-making tools. These will be communicated to patient groups and stakeholders via NHSE communication channels.
Clinicians should continue to follow guidance regarding prescribing of valproate and alternatives for all indications.	Government accepted this action. The NHSE VSIG (https://www.england.nhs.uk/patient-safety/sodium-valproate) is working to reduce the use of sodium valproate in women of childbearing potential. The group has supported implementation of the PPP, which includes access to appropriate contraception and sexual and reproductive

Action for improvement	Progress
	health advice. The group is also working to improve information provision for women of childbearing potential and healthcare workers about the risks of pregnancy while taking this medication. NHSE wrote to all women of childbearing potential who are prescribed sodium valproate to provide information on the risks of pregnancy. The group is also working with the Association of British Neurologists to develop guidance on safely de-prescribing sodium valproate in women of childbearing potential. These risks include sudden unexplained death in epilepsy, relapse and self-harm. The VSIG recommended the development of a national shared care protocol for sodium valproate, as there has been some confusion among prescribers and clinicians regarding responsibilities for monitoring those who use sodium valproate. This has been developed and prioritised in the national care protocol system. Shared care protocols enable GPs to prescribe and monitor medicines or treatments in primary care in agreement with the initiating specialist.
A system similar to the PPP 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.	Government accepted this action in principle. The MHRA accepts the need for robust risk mitigation measures for all teratogens, but the exact measures will depend on the risk associated with the medicine in question and its intended use. Understanding how diseases, medicines and vaccines, and other exposures affect the health of pregnant women and their children is an important public health priority. The MHRA has also now expanded the Clinical Practice Research Datalink Pregnancy Register (an algorithmic pregnancy register based on electronic healthcare records) to include

Action for improvement	Progress
	anonymised data on 24.5 million pregnancy episodes across 10 million women, greatly increasing its ability to study rare exposures and outcomes, and thus improving healthcare advice to women. This expanded Clinical Practice Research Datalink Pregnancy Register is being used by the MHRA to study the safety of COVID-19 vaccination during pregnancy and in another study to improve the understanding of dose-exposure-response relationship of hormonal contraceptives.

7. MHRA transformation to put patients first

Transforming culture

Recommendation 6 of the review 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 2021 to 2023, Putting patients first: a new era for our agency (https://www.gov.uk/government/publications/the-medicines-and-healthcare-products-regulatory-agency-delivery-plan-2021-2023) – has initiated a substantial programme of work to:

- improve how it listens and responds to patients and the public
- develop a more responsive system for reporting adverse incidents
- 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.

Progress update

The MHRA has embarked upon an ambitious organisation-wide transformation to ensure it becomes a progressive and responsive patient-focussed regulator of medical products, as outlined in its Delivery Plan 2021 to 2023.

The MHRA has embarked upon an ambitious organisation-wide transformation to ensure it becomes a progressive and responsive patient-focussed regulator of medical products. Its core values include respect, and focussing on patients and the public.

As set out in its Delivery Plan 2021 to 2023 (https://www.gov.uk/government/publications/the-medicines-and-healthcare-products-regulatory-agency-delivery-plan-2021-2023), the MHRA is putting in place a new organisational structure that will:

- improve how it listens and responds to patients and the public
- develop a more responsive system for reporting adverse incidents
- strengthen the evidence to support timely and robust decisions that protect patient safety

Since January 2022, the MHRA has also begun implementing its new integrated 'one agency' structure, bringing together science, research and innovation, healthcare access, and safety and surveillance for both medicines and medical devices.

This organisational transformation includes the appointment of a new MHRA Chief Safety Officer who is accountable for safety and surveillance for all health care products, including medicines and medical devices. As a member of MHRA's board, the Chief Safety Officer is also responsible for ensuring that the agency's response to the review is delivered. The MHRA will look to establish a strong and collaborative relationship with the new Patient Safety Commissioner.

The MHRA has published a new code of practice on managing conflicts of interest for the independent experts who provide advice on decisions about the safety and benefit risk of medicines and medical devices (https://www.gov.uk/government/consultations/consultation-on-a-new-code-of-practice-for-the-expert-advisory-committees). The new code of practice will ensure that:

- experts remain independent and impartial
- the processes to manage conflicts of interest are robust and clear to all
- the role of patients and the contribution they are able to make is clearly defined, and they are properly supported to contribute effectively

The publication of the code of practice on 8 September 2022 followed a 6-week public consultation where respondents overwhelmingly approved the proposed improvements. A government response to the consultation was published alongside the code of practice.

The MHRA has also completed an internal review of policies and procedures on conflicts of interest to ensure these remain robust – for example, staff cannot hold financial interests, employment or directorships in the pharmaceutical and healthcare industries, or carry out consultancy or other private work for those industries.

Patient involvement

The MHRA's organisational transformation put patient involvement at the centre of its new approach. Its new strategy commits to engaging and involving the public and patients along the regulatory journey.

The MHRA's Patient and Public Involvement Strategy 2021 to 2025 (https://www.gov.uk/government/consultations/mhra-patient-involvement-strategy-consultation) was published in September 2021 and is an important part of the response to recommendation 6 of the review. The strategy has been developed in consultation with patients to understand what was important to them and included input from the review's independent Patient Reference Group, which was established to inform the 2021 government response.

The MHRA will develop and introduce new systems, processes and training to ensure its teams have a means of engaging and involving patients and the public, embedding the patient and public voice in decision-making. The MHRA will work across the health sector to improve the effectiveness of patient engagement and share patient insight. A patient outcome evaluation framework will provide the agency with a robust understanding of progress in delivering the MHRA's vision of being a patient-focused regulator.

Work is underway delivering the strategy and the MHRA will continue to listen to patients throughout the delivery of it.

The MHRA uses a variety of mechanisms to support patient involvement in regulatory decisions. For example, in November 2021, an Expert Working Group for the CHM, which included patient representatives from Allergy UK, the Anaphylaxis Campaign and individual patient carers, made recommendations to MHRA to improve safe use of adrenaline auto-injectors.

Throughout 2021 and early 2022, the MHRA ran 2 workshops (36 attendees), a survey (2,262 respondents), 10 focus groups (54 participants) and a Citizen's Jury across 4 locations UK-wide (98 participants) about a new biobank to investigate the role of genetics in adverse drug or vaccine reactions.

In the last year, the MHRA has made changes to how public consultations are run to enable more patients to contribute. Changes include:

- changing the structure of consultations so patients can jump to the sections that are of most interest to them
- ensuring the language used is accessible to non-experts
- promoting the consultations to relevant audiences

The MHRA has also embedded patient involvement in the Innovative Licensing and Access Pathway (https://www.gov.uk/guidance/innovative-licensing-and-access-pathway), which will give patients faster access to new medicines. A dedicated Innovative Licensing and Access Pathway Patient and Public Reference Group, made up of patients and patient representatives, provides valuable expertise and insight from their patient perspective. Members of the Patient Reference Group sit on the Innovative Licensing and Access Pathway Steering Group, contributing to the decision as to whether to accept an application onto the pathway. The MHRA shares patient insight back with the developer, and encourages them to engage with a wider range of patient groups for diverse input and consider patient-reported outcomes and other measures to ensure the medicines in development offer the best outcomes for patients.

Improving adverse event reporting

The MHRA is undertaking a major investment programme to upgrade its safety reporting systems.

MHRA's SafetyConnect programme is using new technology to improve its responsiveness to patients and a new modern vigilance database using artificial intelligence to support the more rapid identification of product quality defects and safety signals across medicines, medical devices and blood products. Throughout the development of the new system, the MHRA has engaged with patients and the public directly to gain user feedback and perceptions on the system via user needs sessions.

The upgraded reporting system is now at an advanced stage of testing prior to full implementation and the SafetyConnect programme will continue to enhance the service over the coming months.

A new Yellow Card (https://yellowcard.mhra.gov.uk/) website went live in February 2022, building on the improvements made to the Coronavirus Yellow Card (https://coronavirus-yellowcard.mhra.gov.uk/) site that was deployed in May 2020 and enhanced throughout the pandemic.

Other recent enhancements include installing new functionality that enables patients to update their own reports and the MHRA to raise requests for additional information from reporters. These changes have enabled the integration of Yellow Card (https://yellowcard.mhra.gov.uk/) into other services such as the NHS App. The website has been made easier to use with new search and help functions as proposed by patients. There is also a new news feed area so users can keep up to date with the latest research and analysis coming from the Yellow Card data.

MHRA will continue to use patient feedback to add new features to the Yellow Card website to further improve its usefulness, and ease of use for patients and carers.

Strengthening the regulatory framework for medicines and medical devices

Medical devices legislation

Following the UK's exit from the European Union, the MHRA is undertaking an ambitious programme of legislative reform. This provides an opportunity to fully embed the changes recommended by the review.

The review was a key driver for the Medicines and Medical Devices Act 2021 (https://www.legislation.gov.uk/ukpga/2021/3/enacted). Powers in the 2021 act allow the MHRA to amend the Medical Devices Regulations 2002 (https://www.legislation.gov.uk/uksi/2002/618/contents/made), which govern medical devices regulation in the UK, to improve safety for patients and align with the best international healthcare standards.

The MHRA held a public consultation on proposals for a future medical device regime (https://www.gov.uk/government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom), which closed in November 2021. The government published its response to the consultation on 26 June 2022. Analysis of the 900+ responses identified a strong support for proposals that will enable MHRA to improve patient safety.

The MHRA plans for the future regulatory framework for medical devices to:

- improve and safeguard public health
- better assure the safety and quality of devices placed on the UK market
- deliver on the need for improved regulation of implantable devices highlighted by the review

It will be built on 5 strategic pillars:

1. Strengthening the MHRA's power to act to keep patients safe and strengthen safety systems by putting patients at the heart of devices regulation.
2. Making the UK a focus for innovation: the best place to develop and introduce innovative medical devices.
3. Addressing health inequalities and mitigating biases throughout product life cycle.
4. Proportionate regulation that supports businesses through access routes that build on synergies with both EU and wider global standards.
5. Setting world-leading standards – building the UK Conformity Assessed marking (https://www.gov.uk/guidance/using-the-ukca-marking) as a global exemplar.

Given the breadth of the consultation response and level of ambition, the MHRA now intends to lay a statutory instrument to provide the legal basis for the changes from 2023. It will ensure the healthcare system and sector has adequate time to ready itself, reducing the risk of critical supply issues.

Since January 2021, all medical devices have been required to be registered with the MHRA before they can be placed on the market in Great Britain. This has enhanced MHRA oversight of all devices being sold in Great Britain for the first time, supporting its safety surveillance activity and allowing more rapid action where safety concerns are identified. The new medical devices legislation will also mandate manufacturers to submit additional data to the registration system to improve data and availability.

The MHRA is also working on a new policy for a significantly enhanced transparency regime for medical device regulation. The MHRA is scoping this work, and will be delivering key elements over 2022 to 2023 and 2023 to 2024.

Medicines regulation

Powers in the Medicines and Medical Devices Act 2021 (https://www.legislation.gov.uk/ukpga/2021/3/enacted) also allow the MHRA to update the legislation that governs UK medicines regulation. This is being undertaken to:

- ensure safe access to new products
- improve safety for patients
- align with the best international healthcare standards

The MHRA's early access to medicines scheme (https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams) statutory instrument, which came into force on 15 April 2021, gives patients with life-threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation, when they have a clear unmet medical need. The new provisions clarify the legal basis for the early access to medicines scheme and strengthen safety measures for supply of innovative medicines to patients who need them, prior to full authorisation.

Following a public consultation (https://www.gov.uk/government/consultations/consultation-on-proposals-for-legislative-changes-for-clinical-trials) that closed in March 2022, the MHRA is developing legislation to overhaul the UK's clinical trial framework. The ambitious proposals will:

- ensure patients remain at the heart of clinical research and get access to safe, new treatments faster
- promote the UK's status as a world leader in trials, supporting innovation and increased global competitiveness

The consultation also included proposals to encourage the inclusion of under-served populations – including pregnant and breastfeeding women – and increase diversity in clinical trial populations.

The Health and Care Act 2022 (https://www.legislation.gov.uk/ukpga/2022/31/contents/enacted) provides the power to establish a UK-wide medicine information system by NHS Digital. This will

enable the collection of data for the MHRA to establish and maintain medicines registries, which will improve the health and social care system's ability to monitor medicines and protect patients. Registries could also be used to generate high-quality evidence regarding medicine use, benefits and risks to:

- inform regulatory decision-making
- support local clinical practice
- provide patients and prescribers with the evidence they need to make better-informed patient safety decisions

Now that the power has come into force, the MHRA will start scoping how the medicine information system will work in practice, with the goal of developing proposals for public consultation.

Actions for improvement

Action for improvement	Progress
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.	Government accepted this action. The Patient and Public Involvement Strategy 2021 to 2025 (https://www.gov.uk/government/consultations/mhra-patient-involvement-strategy-consultation) was published in September 2021. The strategy has been developed in consultation with patients. The MHRA is working to deliver this strategy and will continue to listen to patients throughout its delivery. The MHRA has expanded its Patient Group Consultative Forum. To date, there are over 180 patients and patient organisations, including members from the review's Patient Reference Group. This forum is designed to help the MHRA engage with patients and patient organisations, and seek their views on a wide range of topics.
To aid public understanding, the MHRA should give detailed reasons for its decisions if they differ from decisions made by another major international regulator.	Government accepted this action in principle. The MHRA may take different regulatory 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 will clearly explain its rationale and the reasons for any differences when the views of other regulators are known.

Action for improvement	Progress
The DHSC should consider if an equivalent of the CHM is needed for devices.	Government accepted this action. The Medicines and Medical Devices Act 2021 (https://www.legislation.gov.uk/ukpga/2021/3/contents/enacted) 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 provide advice on the safety and performance of medical devices, and to strengthen the vigilance system for medical devices. The MHRA has been improving the systems and processes associated with its Devices Expert Advisory Committee. The Devices Expert Advisory Committee is responsible for providing the MHRA with independent, external and expert clinical and scientific input and advice on a wide range of aspects relating to the introduction and safe use of medical devices. Following a review of the Devices Expert Advisory Committee, the MHRA is in the process of establishing an interim Committee on Devices, which will provide advice until a statutory committee is in place. The statutory committee will provide advice on safety and ensure greater involvement of patients as well as scientific, technical, and clinical experts in regulatory decision-making. The MHRA will consult on the proposal for the statutory Expert Committee on Devices during Q3 2022 to 2023 and aims to establish the statutory committee by 2024.
In future, we recommend careful consideration should be given to implementing risk mitigation strategies of international regulators on potential teratogens.	Government accepted this action. The government has carefully considered regulatory approaches for handling the risks of teratogenic medicines. To ensure these remain up to date, the MHRA is conducting a review of its current processes and guidance to establish if any elements can be strengthened. The first stage of this review is scheduled to complete in financial year 2022 to 2023 when its findings will be subject to independent patient and stakeholder input and expert advice, and, if needed, follow-up action and updated

Action for improvement	Progress
	guidance will be carried out in late financial year 2022 to 2023.
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 EWGs** **– whether EWG reports should be reviewed by an independent panel of experts**	Government accepted this action in part. The CHM code of practice on conflicts of interest has been reviewed to ensure it provides ministers, patients and the public with the assurance that decisions made by the commission are impartial. The MHRA has completed a public consultation on changes to the code covering not just the CHM but all of the advisory bodies who provide independent advice to MHRA (https://www.gov.uk/government/consultations/consultation-on-a-new-code-of-practice-for-the-expert-advisory-committees) and aims to implement improvements to the code by the end of the year. The response to the consultation was published in September 2022. The MHRA is reviewing patient representation across all its independent decision-making committees. In addition, as part of the consultation on the new code of practice for its expert advisory committees, the MHRA set out proposals for how the role of patients and the contribution they are able to make is clearly defined, and that they are properly supported to contribute effectively. The government set out the reasons for not using an independent secretariat or independent panel of experts in our 2021 response.

8. The medical device information system (MDIS)

Scoping different ways to achieve MDIS

Recommendation 7 of the review 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 (https://www.legislation.gov.uk/ukpga/2021/3/contents/enacted), which creates a power for the Secretary of State for Health and Social Care to regulate for the establishment of a UK-wide medical device information system (MDIS).

Alongside developing regulations, over £11 million has been set aside for a package of work in 2021 to 2022 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.

Progress update

In 2021 to 2022, a scoping exercise was undertaken to determine how best to deliver an MDIS. This provided a significant amount of learning.

In England, we concluded that expanding the coverage and breadth of existing outcome registries will best deliver harmonised data collections that contain patient, device and outcome-level data.

We have an ambitious target to increase outcome registry coverage from 15% to 80% of Class III implants and Class IIb therapeutic devices over the next 3 years.

We are working with the devolved governments to develop a UK-wide approach that will enable secure data sharing, system interoperability and UK-wide coverage where it is appropriate to do so.

The principles of MDIS could be achieved through a variety of very different data capture, scope, storage and processing approaches. For example, building a

new, standalone product is a different approach to harmonising, expanding and linking to existing registries.

Throughout 2021 to 2022, we scoped the different ways of achieving MDIS, including trialling competing approaches to assess their relative merits. Key learnings from this exercise include:

- diversity of clinical practice, specialist data and organisation structure make standardising approaches very difficult. Data is currently gathered in different locations, via different systems and to different levels of granularity depending on the specialist area and organisational structure. Bringing all that data together while ensuring data governance is very complex. The implementation of a single system across multiple healthcare organisations, including the independent sector and the devolved governments, adds even further complexity. The MDIS outcomes of improving data collection and secure aggregation are best approached by firstly building upon existing points of data aggregation in the system – for example, outcome registries
- digital maturity is critical, and not all trusts will be starting from the same point in terms of the technology they use on a day-to-day basis
- clinical communities recognise and buy in to the value of specialist registries – as these are proven existing systems from which they see benefits – and are willing to commit time and energy to their development. The development of broad data capture mechanisms would require new and potentially more significant engagement on their part to set them up, making broad buy-in potentially less likely

While possible to deliver on traceability and patient outcome objectives by developing a single infrastructure, this risks duplication and disruption of data submission and processes already in place in activities working to keep patients safe.

The DHSC and NHSE therefore concluded that, for England, achieving the MDIS priorities of traceability and patient outcomes through enhancing proven registry processes is beneficial over developing a new standalone infrastructure and processes. The new registry processes will retain the option to deliver a standalone infrastructure should that be required in the future, but will be unified under one platform.

We are working with the devolved governments towards agreeing a UK-wide approach that will enable secure data sharing, system interoperability and UK-wide coverage where it is appropriate to do so.

Delivering a medical device information system

The conclusion of extensive scoping work over the past year is that rapidly expanding exemplar device-level registry coverage across specialties is the most effective and efficient way to deliver a system that allows us to record and assess device safety and patient outcomes in England.

The exploratory work highlighted the challenges of establishing a centralised UK-wide database, given the differing strategies, baselines and progress to date UK-wide. Given these different starting points across nations, we are working with the devolved governments to develop an approach that can build on existing work programmes UK-wide and enable secure data-sharing and system interoperability, and UK-wide safety and outcomes analysis, where it is appropriate to do so.

We have an ambitious target to extend the scope of outcome registries in England from 15% to 80% coverage of Class III implants and Class IIb therapeutic devices over the next 3 years. There will be a single unified outcome registry platform covering the priority medical specialties and therapeutic areas, which will be prioritised based on patient and clinical risk.

We are fortunate to have exemplar registries with world-leading expertise, which provide a template for the analysis and review of devices to support rollout across all specialties. In particular, the National Joint Registry, National Institute for Cardiovascular Outcomes Registry and National Vascular Registry are widely regarded as setting international best practice in analysing outcomes for device procedures.

There are already 600,000 to 700,000 patients a year being recorded with device details in these exemplar registries. This provides a springboard for us to extend the scope of registries as a proven, sustainable approach to collecting data, which is critical given the variable digital maturity and data collection resource across providers.

In addition, NHSE will be exploring ways of making electronic registry data submission easier and accelerating the adoption of barcode scanning through the Scan4Safety programme and automation technologies.

NHSE Outcomes and Registries programme

In May 2022, the recommendations of the MDIS 2021 to 2022 discovery work passed to a new Outcomes and Registries programme led by NHSE. This programme is taking forward the work to expand the outcome registries. NHSE has been working to establish the programme at pace, including:

- governance
- patient representation
- clinical leadership
- a technology platform
- a coverage roadmap to deliver patient-centred change

One primary focus of the programme is to improve oversight and co-ordination. Work to date in this area has included the development of an independent advisory board to challenge and advise the programme’s progress and direction, as well as to continue the form of patient, charity and system-wide engagement that has been successful in the review.

NHSE has also established specialty-level clinical steering boards in the top 10 medical device specialties that account for over 80% of implant usage, ensuring alignment between national clinical leadership and Royal Colleges and specialist societies to drive change.

In parallel, the development work for the rapid expansion of the registries has been progressing. This has included the development of a new medical device-level registry platform architecture. NHSE has been testing the speed of the development and rollout of new registries via a pilot ENT-Cochlear Implant Registry. The Pelvic Floor Registry has been transitioned to NHSE and the new platform has improved PROM usability and device data capture.

NHSE is also in the process of transitioning several registries to the new platform, including the Breast and Cosmetic Implant Registry and the Hip and Knee PROMs. Expansion and improved data usage in the new platform has been taken forward for existing exemplar registries that cover around 3 million patients (for example, cardiology and vascular surgery). NHSE has also been doing early specification development with the NHS app to enable data flow back to patients and with primary care solution providers that will better link primary care records.

Legislating for MDIS under the Medicines and Medical Devices Act 2021

Given our intention to deliver MDIS by expanding the existing registry coverage across specialties in England, we do not currently plan to make use of the powers legislated as part of the Medicines and Medical Devices Act 2021 (https://www.legislation.gov.uk/ukpga/2021/3/contents/enacted).

We will, however, retain the powers in the 2021 act and may use them in future if appropriate to do so.

Next steps

We are committed to delivering on traceability and patient outcomes priorities. In England, this will involve rapidly expanding the outcome registries so that coverage of Class III implants and IIb therapeutic devices increases from 15% to 80% over the next 3 years.

We are working with the devolved governments towards agreeing a UK-wide approach to patient safety and outcomes in medical device procedures, building on the progress being made by each devolved government on their own traceability and safety programmes.

We are building upon the work of the MDIS scoping exercise and taking forward the learning into the new NHSE Outcomes and Registries programme.

Actions for improvement

Action for improvement	Progress
Where the patient gives permission, an adverse device report should be linked to the patient-identifiable database of implanted devices.	Government accepted this action in principle. In England, rapidly expanding exemplar device-level registry coverage across specialties (with device recording) is the most effective and efficient way to deliver a system that allows us to record and assess device safety and patient outcomes. We will integrate this as we expand the breadth of the registries.
A public-facing unique device identification (UDI) database for UK devices based on the Global Unique Device Identification Database (GUDID) (https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/global-unique-device-identification-database-gudid) should be scoped.	Government accepted this action. Since January 2021, all medical devices have been required to be registered with the MHRA before they can be placed on the market in Great Britain. This has given the MHRA oversight of all devices being sold in Great Britain for the first time, supporting its safety surveillance activity and allowing more rapid action where safety concerns are identified. New legislation will require device manufacturers to submit additional data to the registration system, improving data quality as well as ensuring the system's information is accessible to the public.
We recommend a publicly searchable database of adverse events for both medicines and devices.	Government accepted this action. MHRA's SafetyConnect programme is using new technology to improve its responsiveness to patients. Under the SafetyConnect programme, the new Yellow Card (https://yellowcard.mhra.gov.uk/) website went live in February 2022 using modern technology to improve accessibility, scalability and adaptability. The first of a series of over 100 individual improvements were deployed in May 2022 including the ability to allow attachments for medicines and vaccine reports, and support for smart forms based on conditional logic.

Action for improvement	Progress
	Deployment of the core technology programme has been separated into different phases, with the safety database, data platform and enhanced industry incident reporting systems for medical devices going live in early December 2022. This phase will fully integrate the new Yellow Card with the safety database and enhance 2-way communication between the MHRA and device manufacturers on individual incidents. Further deployments in 2023 will include the safety database for medicines and enhanced signal detection approaches for all products.
Databases and subsequent registries should embrace the private or independent health care sector as well as the NHS.	Government accepted this action. In England, we will expand the outcome registries that contain patient and device-level data. We have an ambitious target to extend the scope of registries to 80% coverage of high-priority implant procedures over the next 3 years. The independent sector continues to be an important partner to deliver care for patients, particularly as we move forward to tackle the COVID-19 backlog of elective care. Through both this work and work to address the findings of the Paterson Inquiry (https://www.gov.uk/government/publications/paterson-inquiry-report), the government is working to ensure a single-system approach is taken towards healthcare regulation and information. One example of this is the Acute Data Alignment Programme, working between the NHSE National Consultant Information Programme and the Private Healthcare Information Network. This programme is piloting approaches to achieve alignment of data collection and analysis between the NHS and independent sectors.
Patient-reported measures such as PROMs and PREMs should become common currency in the	Government accepted this action. PROMs and PREMs are used to assess the quality of care delivered to NHS patients from the patient perspective. PROM data has been

Action for improvement	Progress
assessment of the benefits and risks of current and new interventions.	collected by all providers of NHS-funded care since April 2009 and currently covers 2 clinical procedures: hip and knee replacements. NHSE will be working to expand the coverage of PROMs and PREMs across specialties and procedures as the registries develop, ensuring integration of registries data with PROMs or PREMs data. For mesh specifically, an interim patient questionnaire that includes both PROMs and PREMs is being developed by NHSE and NHS Digital to ensure high-quality data is collected within the specialist mesh centres. This is pending the development of a validated PROM for pelvic floor disorders, which has been commissioned by the NIHR (https://www.nihr.ac.uk/documents/21583-patient-reported-outcome-measures-proms-for-pelvic-floor-disorders-commissioning-brief/29590). The PROMS private pilot alpha commenced in May 2022. Private pilot beta is due to commence in November 2022 and the public pilot will end in January 2023. NHSE has established an 'experience of care' sub-group of the Executive Quality Committee and is in discussion with DHSC on how experience of care will feature in the NHS Long-Term Plan (https://www.longtermplan.nhs.uk/) update.
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.	Government accepted this action. In England, we will develop an Outcomes and Registries programme and data platform with data collections that contain patient outcome and device-level data. In England, this will involve rapidly expanding the outcome registries (with device recording) so that coverage of Class III implants and IIb therapeutic devices increases from 15% to 80% over the next 3 years. We are working with the devolved governments to develop a UK-wide approach to patient safety and outcomes in medical device procedures, building on the progress being made by each

Action for improvement	Progress
	devolved government on their own traceability and safety programmes. We will be including patient representation and involvement alongside clinical leadership throughout the Outcomes and Registries programme, from oversight through to the development of data collections and reporting outputs.
Every child's NHS number should be entered on their school attainment record on year of entry.	Government accepted this action in principle. From April 2022, the Department for Education, DHSC, Department for Levelling Up, Housing and Communities, and the Home Office are working together to identify enablers of appropriate information-sharing by professionals working with children and families, such as consistent identifiers, improved standards and guidance. The Department for Education will publish a report setting out the government's policy on information-sharing to safeguard children, including considerations of issues around applying a consistent child identifier.

9. Conflicts of interest

Lists of doctors' interests

The first part of recommendation 8 states:

> " Transparency of payments made to clinicians needs to improve. The register of the 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 interests, and that this information is published locally at employer level.

Progress update

Ongoing.

We expect to have a UK-wide system for doctors to declare their interests in 2023, following pilots this year. Once we have a system in place for doctors, we will consider systems for other healthcare professionals.

We want to ensure that doctors declare their competing interests and that healthcare providers publish this information for patients at a local level.

We are working with the devolved governments to ensure a UK-wide approach and will implement a system for doctors to declare their interests first, before considering the requirements for other healthcare professionals.

Doctors are already required by the GMC to declare their competing interests. The GMC's good medical practice sets out the standards required of all registered doctors including "honesty in financial dealings" (https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice/domain-4---maintaining-trust#paragraph-77). This guidance is made under powers in the Medical Act 1983 (https://www.legislation.gov.uk/ukpga/1983/54/contents). The GMC can and has taken action against doctors who fail to meet these requirements, and serious or persistent breaches that pose a risk to patient safety or public trust can put a registrant's registration at risk.

Since January 2022, DHSC has run a series of working groups with the devolved governments, as well as representatives from the NHS in England, Scotland and Wales, Health and Social Care in Northern Ireland, the independent sector, the GMC, the CQC, and equivalent organisations UK-wide. We have also established a Patient Representative Working Group to ensure the system implemented is designed in a way that meets patient needs.

In the working groups, we have developed standardised temples and guidance to ensure there is consistency in the information that is collected and published on doctors' interests. Processes may differ between organisations, but the information made available to patients by healthcare providers should be the same UK-wide. We are also working to ensure there is effective oversight of publications of doctors' interests across the UK.

We are now in the piloting phase of implementation and systems are being trialled UK-wide. The main criteria to assess in the pilot are the:

- feasibility and cost of establishing and maintaining systems across different healthcare settings
- content of standardised templates and guidance

- accessibility of information for patients

During the pilot, we will be seeking feedback from healthcare providers, doctors and patients. Full implementation will be in 2023, subject to a successful review of the pilot systems.

Once we have a system in place for doctors, we will consider the requirement for establishing equivalent systems for other healthcare professionals. We will work with professional regulators to consider which healthcare professionals have the highest risk for a competing interest to arise.

We will ensure expectations around how relevant healthcare professionals should act in relation to declaring and managing their competing interests are clearly set out.

Mandatory reporting for industry

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 industries, and we are exploring options to expand and reinforce current industry schemes, including making reporting mandatory through legislation.

Progress update

Industry representatives have been engaged for their views and we are working to develop next steps.

We have also legislated through the Health and Care Act 2022 (https://www.legislation.gov.uk/ukpga/2022/31/contents/enacted) to enable the Secretary of State for Health and Social Care to make regulations if required.

We have conducted a phased engagement plan with industry, patients and professional regulators to inform our work and understand the impact new regulations would have on different stakeholders. This work included collaboration with 14 trade associations, professional regulators and the Patient Reference Group, as well as others.

In the first phase (August 2021 to January 2022), we updated trade associations on our plans to put reporting of industry payments on a statutory footing.

In the second phase (February to April 2022), we discussed our goals with industry stakeholders and professional regulators, gathering initial feedback on the key factors to consider as we develop next steps.

In addition, we legislated through the Health and Care Act 2022 (https://www.legislation.gov.uk/ukpga/2022/31/contents/enacted) to enable the Secretary of State for Health and Social Care to make new regulations. These enabling powers would allow the government to introduce regulations requiring the reporting of this information in the future, as necessary.

Next steps

The government is reviewing the information gathered from stakeholders to develop plans on how best to deliver on the objectives of the recommendation.

Actions for improvement

Action for improvement	Progress
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. While 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.	Government accepted this action. In September 2022, following a 6-week public consultation, the MHRA published a new code o practice on managing conflicts of interest for the independent experts who provide advice on decisions about the safety and benefit risk of medicines and medical devices (https://www.gov.uk/government/consultations/consulta on-a-new-code-of-practice-for-the-expert-advisory-committees). The new code will ensure that: – experts remain independent and impartial – the processes to manage conflicts of interest a robust and clear to all – the role of patients and the contribution they ar able to make is clearly defined, and that they are properly supported to contribute effectively
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	Government accepted this action in principle. Our 2021 response outlines our approach to implementing this recommendation. Both the NIHR and UK Research and Innovation are signatories to the Concordat to Support Research Integrity

Action for improvement	Progress
(https://www.wame.org/conflict-of-interest-in-peer-reviewed-medical-journals).	(https://www.universitiesuk.ac.uk/topics/research-and-innovation/concordat-support-research-integrity). The concordat 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.
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 that is detrimental to patient safety. This should apply in the private or independent sector as well as in the NHS.	Government accepted this action. All licensed doctors are required to participate in annual appraisals for revalidation and to collect supporting information about their practice as pa this process. We continue to work with the GMC to ensure the guidance on supporting information for appraisal and revalidation (https://www.gmc-uk.org/registration and-licensing/managing-your-registration/revalidation/guidance-on-supporting-information-for-appraisal-and-revalidation) is consiste adopted by both NHS and independent provider
The GMC should be alert and act if any doctor's practice causes concern in respect of failure to follow guidance.	Government accepted this action. The GMC states that serious or persistent failure follow Good medical practice (https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/go medical-practice), and all the guidance that stems from it, will ultimately put a doctor's registration a ability to practise at risk. The GMC can only act when concerns are brou to its attention. The GMC's focus is therefore on promoting the reporting of concerns through a range of routes. The GMC continues to encourage healthcare professionals to raise concerns through its Speaking up (https://www.gmc-uk.org/ethical-guidance/ethical-hub/speaking-up) hub, as outlined ir our 2021 response. In addition, the GMC has reframed the professio behaviours and patient safety programme to foc

Action for improvement	Progress
	on maternity safety. The GMC is working with the NHSE Culture Working Group and regional perinatal oversight groups to shape and improve maternity culture. As part of this, the GMC is delivering professiona behaviour patient safety sessions for targeted maternity units in partnership with the Nursing ar Midwifery Council. It plans to deliver these sessi in all 7 areas of England by the end of this year. The GMC is also now transitioning work on Supporting a profession under pressure (https://www.gmc-uk.org/-/media/documents/somep-20 -chapter-1_pdf-81119234.pdf) (PDF, 177KB) into its business-as-usual activities. The data and resea from each of the 3 core independent reviews (https://www.gmc-uk.org/about/how-we-work/corporate-strategy-plans-and-impact/improving-understanding-of-healthcare-environments) commissioned as part of Supporting a profession under pressure program – Caring for doctors, caring for patients (https://www.gmc-uk.org/-/media/documents/caring-for-doctors-caring-for-patients_pdf-80706341.pdf) (PDF, 1.9MB), Fair to refer? (https://www.gmc-uk.org/-/media/documents/fair-to-refer-report_pdf-79011677.pdf) (PDF, 1.9MB) and the Independent review of gross negligence manslaughter and culpable homicide (https://www.gmc-uk.org/-/media/documents/independent-review-of-gross negligence-manslaughter-and-culpable-homicide---final-report_pd-78716610.pdf) (PDF, 2.8MB) – informed t GMC's 2021 to 2025 corporate strategy (https://www.gmc-uk.org/about/how-we-work/corporate-strategy-plans-and-impact/corporate-strategy), and its ongoing work to promote equality, diversity and inclusion.
Hospitals should encourage clinical audit and should have robust systems for monitoring quality at board level. The CQC should also assure itself that hospitals – both in the NHS and in the	Government accepted this action. Our 2021 response outlines our approach to implementing this action for improvement. The CQC is currently developing its new regulat model, which will be underpinned by a new singl assessment framework (https://www.cqc.org.uk/abo

Action for improvement	Progress
private sector – have robust quality assurance programmes including following appropriate guidance.	us/how-we-will-regulate/single-assessment-framework) part of this single assessment framework, the CC will continue to assess the robustness of quality assurance programmes.
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.	Government accepted this action in principle. Our 2021 response outlines our approach to implementing this action for improvement. NICE has provided advice on how to safely introduce new procedures into clinical practices (https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-interventional-procedu guidance). The responsibility for training programmes lies w 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.	Government accepted this action in principle. Our 2021 response outlines our approach to implementing this action for improvement. Under the Health and Social Care Act 2008 (https://www.legislation.gov.uk/ukpga/2008/14/contents) providers of regulated activities, including NHS a independent providers, must register with the CQ and follow a set of fundamental standards of saf and quality below which care should never fall. T CQC can take enforcement action to prevent an further harm or risk of harm to patients and other members of the public.

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