FDNH APPG – IMMDS Review Questions

Recommendations three/four – Redress

1. If I understood correctly Nadine mentioned the Redress Agency will not give the answer she wants. What is the answer she wants?

2. They were not given access to justice because the legal mechanisms weren't available. given that these legal grey areas will continue to exist, how will families, from that time and any new cases, gain access to redress? will the patient safety commissioner have the power to do this?

3. My daughter was part of the FAC litigation in 2010, which lost legal aid funding because it was not likely to succeed.

4. An effective redress scheme for mesh sufferers, funded by the manufacturers of “flawed” mesh, is possible if the evidence of defects is brought forward. “Mesh” retraction into the vulva is a particular feature of one type of mesh (CR Bard). That can easily be proven by MR! scans of affected women ! There may be others.

5. Why are the Government not setting up a redress agency? We have lost our jobs, homes, and are struggling financially!

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10. Why are the Government not setting up a redress agency? We have lost our jobs, homes, and are struggling financially!

    Answer: I deeply sympathise with patients and their families who not only feel that they have suffered adverse outcomes to these interventions, but who also feel that their voices were not heard.

    Routes are available if patients believe they were harmed by medicines or medical devices. They can either bring a legal claim in the courts against manufacturers on the basis of product liability, or against the actions of an NHS provider or clinician.

    The Patient Safety Commissioner will be a 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. It will be up to the Commissioner to determine how best to involve patients in the discharge of the Commissioner’s duties. The Commissioner will not be responsible for or have the power to investigate individual

cases. This function is already the responsibility of a number of existing regulatory bodies.

On recommendation 4, the Government has no current plans to establish a redress agency as announced in the Written Ministerial Statement on 11 January. The Government and manufacturers already have the ability to set up redress schemes and have already done so where appropriate for other products or conditions without establishing an additional agency.

We are focused on preventing harm in the first place: we will improve the safety of medicines and medical devices safety, setting high standards for industry to market and manufacture products, so that harm is less likely to happen in the future.

We do not believe a redress agency in this country would necessarily make products safer or drive the right incentives for industry, because many decisions by pharmaceutical and devices companies are made at a global level.

Relocating existing ex gratia schemes behind a new single front door would not, of itself, change or align the rules of individual schemes; changing any of the schemes would need to be a specific exercise with its own costs and benefits.

Recommendation four on redress schemes for the three individual products is still being considered.

Recommendation six – MHRA Reform

1. The Cumberlege Review recommended that MHRA needs substantial revision particularly in relation to adverse event reporting and medical device regulation. Yet the Medicines and Medical Devices Bill appears to give freer reign to the MHRA, with talk of deregulation and encouraging innovation. Surely this is at odds with the recommendation of the Cumberlege Review?

Answer: Secondary legislation made under the Bill, is strictly limited to the matters described on the face of the Bill. The powers in the Bill ensure the MHRA can strengthen the regulatory system for the better protection of patients and the public. Without the ability to amend and update the regulatory regimes that currently exist, the UK would be stuck with a stagnant regime and unable to take appropriate and proportionate steps to address patient safety concerns.

There is a duty on the face of the Bill for the Secretary of State to conduct a public consultation before making regulations, and we must have regard to patient safety, availability and the favourability of the UK before regulations are made to change our existing regulatory frameworks.

Innovation and patient safety are not mutually exclusive, and the powers in the Bill are essential to ensure that the MHRA's regulatory frameworks facilitate both. We want to ensure patient access to new potentially life-changing technologies, and that patient safety is at the heart of everything the MHRA does.

The Bill ensures regulations will not put patient safety at risk, through the Government amendment that introduced both an overarching objective of safeguarding public health and a 'lock' on regulatory changes with an impact on safety to make absolutely clear that safety on public health can only be affected where the benefits outweigh the risks.

History has shown us the risk of taking narrow powers in areas where technology and innovations move quickly, and where the inability to regulate quickly can significantly delay our response.

2. The IMMDS Review says that the Mhra needs to be overhauled and to regulate devices better but the medicines and medical devices bill is actually giving more power and freedom to the MHRA

3. Are the government going to enact the Cumberlege recommendations on reform of MHRA?

4. Baroness Cumberlege called for an "overhaul" of the MHRA in her speech last July. Are we expected to simply accept the MHRA's words that they will improve engagement and that the patient voice will be at the heart of everything they do? They have been self-governing since their inception and there have been many allegations of corruption, revolving doors etc. When will the Government start to fully regulate the Regulator?

Answer: The MHRA is an executive agency of the Department of Health and Social Care. It is accountable to the Department and Ministers.

The Government has accepted the recommendations on revision of the MHRA and so has the Agency itself. The MHRA has already begun a substantial programme of work to improve how it involves patients in all aspects of its work, to reform systems for reporting adverse incidents with medicines and medical devices, and to strengthen the evidence base for its regulatory decisions.

Valproate

1. As Valproate continues to be prescribed to women of child bearing age and the Pregnancy Prevention Programme (Prevent) continues to fail and reach women, with the DHSC consider replacing the QOF for conception counselling etc to ensure they receive the warnings and information needed.

Answer: Firstly, I would like to convey my most sincere sympathies to anyone who has suffered as a consequence of taking sodium valproate during pregnancy. We have seen a gradual decline in prescribing of valproate to women of childbearing age over a number of years but recognise that more needs to be done to reduce prescribing to the minimum.

The Pregnancy Protection Programme was implemented in April 2018 and since then the MHRA have been monitoring its uptake and seeking feedback on its effectiveness. The MHRA is working with the professional regulators to create a cross-organisational Valproate Safety Implementation Group to drive forward compliance with the plan.

The MHRA are absolutely clear that valproate must not be prescribed to any woman or girl of child-bearing potential unless she has a Pregnancy Prevention Programme in place. In addition, the MHRA is working with NHS Digital to establish a registry to monitor adherence to the Pregnancy Prevention Programme and allow for long term individual patient follow-up. The aims of this registry will include tracking the healthcare of women prescribed valproate but also ensuring data is captured on any children they might have while taking it. This will enable their developing and needs to be much more fully understood. When fully developed, the registry will be accessible to relevant stakeholders, including patients and their children allowing them to actively contribute data.

On replacing the Quality Outcome Framework for contraception, one of Baroness Cumberlege's Actions for Improvement was to, 'introduce an indicator on safe prescribing in pregnancy for future iterations of the Quality and Outcomes Framework'. We are giving this

careful consideration and will provide a response as part of the Government's full response to this Report.

Recommendation five/Mesh

1. The pelvic floor association (set up by the dismissed surgeon from Bristol) - is planning to implement an enhanced consent form. We have been party to the form and made our thoughts known for additions to the form, however, they haven't issued these forms yet.

Answer: I am unable to comment on the consent forms developed by the pelvic floor association. However, the GMC's revised guidance on decision making and consent, for both written and verbal consent, came into effect on 9 November. This encourages doctors to be open with their patients about uncertainties, to answer questions honestly and to share all relevant information with patients about potential benefits and harms of each option so they can make informed decisions about their care. It advises doctors to record a summary of discussions with a patient, to be made available both to the patient and those involved in their care, and make sure that when a patient gives consent, this is recorded in their notes. It states that doctors should accommodate a patient's wishes if they would like to record the discussion themselves.

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2. Can Nadine ensure the new study for which I have sent a link on erosion of mesh be read by her team and commit to exploring funding for further research and testing as recommended by this study to ensure patient safety?

Answer: I believe the study referred to is, *Long-term mesh erosion rate following abdominal robotic reconstructive pelvic floor surgery: a prospective study and overview of the literature*. I would like to reassure you that the Government recognises the importance of research into mesh and closely monitors research and evidence produced on a wide variety of topics to inform policies and decisions.

The National Institute for Health Research (NIHR) is funded through the Department of Health and Social Care to improve the health and wealth of the nation through research. The NIHR welcomes funding applications for research into mesh. These applications are subject to peer review and judged in open competition, with awards being made on the basis of the importance of the topic to patients and health and care services, value for money and scientific quality. It is not usual practice for the NIHR to ring-fence a proportion of its budget for research into particular topics or conditions.

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3. The mesh specialist centres, due to begin work in April - have these locations been confirmed as yet please?

4. When will these centres be implemented?

Answer: The mesh centres will be going live from 01 April 2021, the names and locations of mesh centres were announced on Tuesday 02 April. The Centres will be in:

- Newcastle Upon Tyne Hospitals NHS FT
- Sheffield Teaching Hospitals NHS FT
- Manchester University NHS FT
- Cambridge University Hospital NHS FT
- University College London Hospitals NHS FT

- University Hospitals of Leicester NHS Trust
- Nottingham University Hospitals NHS Trust

No bids were initially received from the South East and South West; however, providers have now come forward and NHS England will establish services in South East and South West regions as soon as possible.

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5. Women's mesh should be "blanket" banned. The clinicians are pursuing their own interests. There are other alternatives in most clinical circumstances.

6. And did you know that patients are still receiving this mesh (on high vigilance) and being told that "it's not the mesh in the news"

7. In light of this new evidence will all mesh use be suspended until further research is concluded to ensure patient safety?

8. New study highlights safety issues of pelvic mesh erosion. "The results produced show that all the commercial products tested were capable of eroding tissue at a significant rate…. This is a clear indication that much further research and testing should be carried out before a surgical mesh is clinically used."
https://www.sciencedirect.com/science/article/pii/S1751616120308171

9. On what evidence have you based your comment on that mesh is safe for some? you specifically mentioned Mesh for men who have hernia, can you share the evidence you have used

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Answer: I have been advised that the current pause in the use of vaginally inserted mesh to treat prolapse and the use of tape or sling to treat Stress Urinary Incontinence constitutes a high vigilance programme of restricted practice to allow the NHS to move towards a consistent, high-quality service that adequately meets the conditions set out by Baroness Cumberlege.

A blanket ban of the relevant procedures was not recommended as there needed to be some exceptions within the pause. NHS England and NHS Improvement is monitoring progress on meeting the conditions of the national pause on vaginal mesh insertion procedures. The pause remains in operation. Changes will only be made following consultation with stakeholders including patients, professional bodies, other NHS organisations, and the Department of Health and Social Care.

The procedures used for hernia repairs are different to those used for vaginal or pelvic prolapse and the mesh is normally used in a different way. In hernia surgery, the mesh is usually placed next to muscle, which is where the hernia occurs. Most hernias occur in the groin and there are no other organs nearby that will come into contact with the mesh. In pelvic surgery organs are attached to the mesh or may become in contact with it. Hence the big difference between hernia and pelvic surgeries is the lower risk of complications in the former. Inguinal hernia repair is one of the most common surgical procedures in the UK, helping thousands of people every year. The benefits and risks of using mesh for hernia repair have been considered by clinicians and the professional bodies who represent them, and their advice is that there remains a clinical need for hernia procedures using mesh. It is a required part of the consent process that the risk of complications from any procedure including use of mesh are discussed with each patient.

In addition, The National Institute for Health and Care Excellence (NICE) has been working with women who have been affected by pelvic mesh complications and healthcare professionals who treat and support them, to produce two patient decision aids. Both patient decision aids will be released for review by stakeholders later this month before final versions are passed to NHS England and NHS Improvement for field testing, once the specialist services are up and running.

NICE has also carried out an exceptional surveillance review on its guideline on the management of urinary incontinence and pelvic organ prolapse in women (NG123) following publication of the IMMDS Review. Given the limited evidence identified on partial and full removals for managing mesh-related complications, it was considered that there is insufficient evidence to trigger an update to the guideline at this time. NICE will continue to monitor the situation and update the guideline if required.

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10. The lifelong, pelvic neuropathic pain in mesh, hysteroscopy pain and “endometriosis” pain (EndoAPPG) ALL Result from injuries to pelvic nerves caused by straining on the toilet (30% pop, 60% mesh pop), difficult 1st labours and gynaecological surgery e.g. evacuation for the uterus

Answer: NHSE England have advised me on both the pain caused as a result of mesh, and pain caused as result of endomitosis.

Firstly, endometriosis is an often-painful disorder in which tissue similar to the tissue that normally lines the inside of the uterus — the endometrium — grows outside the uterus. Endometriosis most commonly involves the ovaries fallopian tubes and the tissue lining the pelvis.

With endometriosis, the endometrial-like tissue acts as endometrial tissue would — it thickens, breaks down and bleeds with each menstrual cycle. But because this tissue has no way to exit the body, it becomes trapped. When endometriosis involves the ovaries, cysts called endometriomas may form. Surrounding tissue can become irritated, eventually developing scar tissue and adhesions — abnormal bands of fibrous tissue that can cause pelvic tissues and organs to stick to each other. Endometriosis therefore causes pain and sometime that is severe, especially during menstrual periods.

Mid urethral tape mesh is used to treat stress urinary incontinence, abdominal mesh is also commonly used to treat prolapse and vaginal mesh has been used to treat prolapse. A small percentage of women have developed complications from mesh surgery, and these include vaginal mesh exposure, extrusion of mesh into the urinary tract, extrusion into the bowel, infection, pain, fistulae and sexual dysfunction.

Finally, on hysteroscopy. I do understand that whilst it is a commonly performed investigation, and most women are able to have the procedure in an outpatient setting without local anaesthesia, it can be associated with significant pain in some women. I have provided further information on hysteroscopy in my response to the hysteroscopy questions below.

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11. the centres set up in 2017 have pro mesh surgeons who are dismissing patients issues. Will the new centres allow surgeons chosen by patients. Trust is a massive issue for those of us who have had issues.

Answer: I have been advised NHSE is working closely with providers to set up the specialist mesh removal centres. It is also working in partnership with the British Association of Urological Surgeons and the British Society of Urogynaecology to ensure that there is a consistent approach to informed consent and shared decision-making in these centres, with clear and accessible information available for patients.

Once in place the specialised services will work closely with women affected by mesh complications consequent to mesh insertion vaginally or abdominally for urinary incontinence and prolapse through providing multi-disciplinary team management. All mesh complications must be discussed at the Mesh Service's Multi-Disciplinary Team which will consist of core members including: 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; and a specialist nurse in urogynaecology, urology or incontinence.

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12. I am still waiting for NHS England to reply regarding no inclusion of Pexy meshes in the new mesh centres

13. Please can I add that it's not just vaginal mesh that is the issue and that there are no named specialist centres for pelvic mesh - namely, rectopexy, sacrocolpopexy mesh which is abdominally placed

14. rectopexy patients have not been included in the new mesh centers . Can I ask why we are overlooked as we have a multitude of issues. I totally agree with Emma , as a bowel patient I have no where to go. My gp is out of his deepth.

Answer: I am truly sorry to anyone who has been has suffered as a result of sacrocolpopexy or rectopexy mesh.

Sacrocolpopexy relates to vaginal vault prolapse and therefore treatment for the removal of mesh fitted during a sacrocolpopexy procedure would be included in the remit of the specialist mesh centres. These centres will be live from 1 April 2021.

On rectopexy mesh, I have been advised that NHS England and Improvement are aware of the issue raised by men and women concerning the removal of mesh fitted during a rectopexy procedure. They are currently exploring the service implications of groups of patients who have had mesh inserted for colorectal indications and who need this removed.

Recommendation 7 – MDIS

1. Establishing a UK-wide medical device information system – when can stakeholders expect an update on details of this and what is the timeframe for establishing this system?

Answer: NHS Digital, working with other system partners, are already developing a comprehensive database for vaginal mesh, as well as other pelvic floor treatments, that can be used to support clinicians and the MHRA to identify emerging patient safety concerns. This has been addressed as a priority, reflecting the experiences faced by women affected by treatment with vaginal mesh and the recommendations of the Independent Medicines and Medical Devices Safety Review. A first version of this system is expected to be operational by Spring 2021 starting with mesh removal centres and expanding to all NHS and private providers undertaking pelvic floor surgery during 2021.

The government is committed to taking steps to ensure that UK patients can access the best, most innovative devices available but also that those devices are safe. The 'First Do No Harm' report, has further emphasised the value to patients in capturing more comprehensive and high-quality information on higher-risk medical devices, particularly devices that are implanted. The Government introduced clause 21 in the Medicines and Medical Devices Bill allowing for regulations that will provide a legal framework for the establishment and operation of a new medical device information system by NHS Digital. The system will cover all patients in the UK, regardless of whether they are treated in an NHS facility or by a private healthcare provider. Delivering a comprehensive, UK-wide approach is an ambitious goal and the Government is working closely with the Devolved Administrations and system partners to carefully consider the regulatory framework needed alongside NHS Digital's operational delivery of the system to make sure that we get this right.

We will be starting informal stakeholder engagement on the regulations shortly with a formal public consultation taking place later this year. This will inform how the first elements of the medical device information system is established under the new regulations.

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2. Given the significant role that pessaries could play in the future management of complex pelvic organ prolapse, and the changes due to Brexit, and the very poor data regulations for the use of pessaries currently - will vaginal Pessary devices be considered in the broader remit of the medical devices group activity?

Answer: The scope of the devices captured by any future medical device information system, and how this might be extended beyond high risk devices, needs to be carefully managed. We will be considering the scope of devices included within the information system and how complex condition management is reflected as part of the development, taking an informed view based on clinical guidance and wider consultation.

Recommendation 8 – conflicts of interest

1. Is the Government going to ensure that mandatory registers of financial conflicts of interest for doctors are held by regulators, as recommended by the Cumberlege review? This was also recommended in 2005 and the Government ignored it then.

Answer: If anyone has felt adequate care has not been provided, anyone has the right to make a complaint about any aspect of NHS care, treatment or service. More information on how to make a complaint about NHS services is available online at https://www.nhs.uk/using-the-nhs/about-the-nhs/how-to-complain-to-the-nhs/. A complaint about service provision may be made to *either* the service provider or the commissioner of the service. The first step will be to raise the matter (in writing, electronically, or orally) with the service provider, or with the commissioner of the service. If local resolution is unsuccessful, you may refer the complaint to the Parliamentary and Health Service Ombudsman.

Additionally, if anyone feels that adequate care has not been given by a medical practitioner during a hysteroscopy, they can raise their concerns with the General Medical Council (GMC) if they have not already done so. Details on the type of concerns the GMC can investigate, how to raise a concern, and the actions it can take to protect public safety and confidence in doctors can be found at www.gmc-uk.org/concerns.

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2. One of the most desperately needed recommendations made by the Cumberlege Review was the recommendation for mandatory reporting from the pharmaceutical and medical device industries of payments made to doctors, and for the GMC to begin to keep list of doctors' financial interests. Will UK drug and device companies be required to publish their payments to medical professionals, as seen in the US following their "Sunshine Act"? Can this happen in the UK without legislation? If not, what plans are there to encourage the government to enact the appropriate legislation?

3. Are the government going to enact legislation to ensure drug and device companies declare payments they make to doctors?

Answer: Recommendation eight on mandatory reporting for the pharmaceutical and medical device industries of payments is currently under consideration.

Recommendation 9 – Patient Engagement Group/Taskforce

1. I also run a mesh group rectopexy mesh victims and support and feel I should be included in the patient panel, I have a vast knowledge and patients stories on all Pexy meshes including my own story. I am still waiting for NHS England to reply regarding no inclusion of Pexy meshes in the new mesh centres .

2. We would urge the Minister to meet with the campaign groups and ourselves on the urgent issue. Women are still suffering with no evidence of the action needed being taken

3. Nadine Dorries- in view of the numbers of requests to join the patient panel and for meetings how do you decide whose request gets accepted?

4. Pleased to hear about the Patients Representative Panel. I represent a women's group. How do we join, please.

5. I also run a mesh group rectopexy mesh victims and support and feel I should be included in the patient panel, I have a vast knowledge and patients stories on all Pexy meshes including my own story

Answer: The Patient Reference Group will ensure that patient voices are heard as we move forward towards a full response to the report. Applications to join the patient reference group were open from 21 January – 8 February. To ensure the opportunity was made available to as many people as possible, the details of how to apply to join the group were circulated to attendees of the First Do No Harm APPG when the application process was initially launched. The details were also posted on the APPG's website following the meeting on 26 January.

DHSC has appointed Traverse, through an open and competitive tender process, to establish and facilitate the Patient Reference Group. Traverse are leading the recruitment process for group members and to ensure the process is fair, they will use a standardised scoring process to review applications and select candidates who demonstrate the appropriate skills and experience for the role, as outlined in the role description.

Primodos

1. It is now clear in the review evidence that the evidence of risk was public in 1973, but that women were simply not informed.
2. Why is the term anecdotal evidence still being used to describe evidence that is not from a professional?

Answer: I am restricted as to what I can say regarding Hormone Pregnancy Tests (HPTs), given the live litigation. As I outlined during the APPG, the Government's position regarding a causal association between HPTs and adverse outcomes in pregnancy is clear. The scientific evidence has been reviewed on a number of occasions, most notably by the Commission on Human Medicines Expert Working Group (EWG) on HPTs who reported their findings in November 2017. The EWG concluded that the available scientific evidence did not support a causal association. This remains the Department's position.

FDNH APPG – Hysteroscopy Questions

1. My question is for Nadine. I had 4 biopsies cut from my womb during a hysteroscopy at Whipps Cross Barts Trust hospital in October with no anaesthetic or pain relief beyond the nurofen I had been told to take at home. I was sent home alone immediately afterwards and ended up going into shock. I now have PTSD from the experience. Mine is far from an isolated case and there are many women like me whose experience and pain scales have not been recorded. Are you going to take any action to put a stop to this barbaric procedure?

2. Good morning. thrilled to see another APPG first do no harm meeting. my question is regarding outpatient hysteroscopy. why are so many women still put through barbaric procedures without pain relief- passing out with pain, screaming, crying and being held down. what can the APPG do to end this? Thank you

3. Is the Minister aware that the operation of so-called "See & Treat" clinics in NHS gynaecology and colposcopy departments, for invasive procedures with significant risks including hysteroscopy or LLETZ, does not meet the standards for informed patient consent as per the Montgomery ruling? And how does she propose to bring these NHS practices into line with the law?

4. Thank you Baroness Cumberlege for asking the hysteroscopy Q. It was great to hear Nadine acknowledge there's a problem with anaesthesia being available for hysteroscopy. As a member of Campaign Against Painful Hysteroscopy we are not aware we've had correspondence from her recently which addresses this important issue, but we would be pleased to hear from her. We need to stop this torture that so many women are forced to endure. I hope that the implications of this for Patient Safety are clear! And I look forward to receiving your reply.

5. will you include a representative from the Campaign Against Painful Hysteroscopy to join the patient panel?

6. The hysteroscopy market is apparently worth a quarter of a billion dollars worlwide and growing. Clearly a significant number of women are subject to hysteroscopy and, in this country, frequently in large numebrs as outpatients without analgesia or anesthesia, leading to avoidably distressing and potentially harmful experiences. Should this not concern the government and the health secretary?

7. Painful hysteroscopy is caused by activation of traumatic microneuromas in the cervix. The pain is NOT treatable. IT is similar to neuropathic pain from mesh and results from similar injuries ot pelvic nerves. The risk is detectable prior to the procedure using the Pipelle test.

8. For Nadine Dorries - Please would you agree there's an inequality between NHS prostate biopsy patients being given MRI to see if they really need painful and invasive biopsy and womb biopsy/hysteroscopy patients being sent direct to outpatient See & Treat with just paracetamol and 'rescue local anaesthetic'?

9. Please will the Minister for Patient Safety meet with the Campaign Against Painful Hysteroscopy?

10. Men are offered MRIs and analgesia before prostate biopsies why are women expected to undergo painful outpatient hysteroscopies without any pain relief?

11. when will you take action to ensure that the DHSC improves pain relief for women undergoing outpatient hysteroscopy

12. Why was the anaesthetic removed from Hysteroscopy without evidence from patient reported outcomes.

13. Dear Nadine Dorries, Thank you for caring about woman's endoscopy. Please will the DHSC introduce regional anaesthesia as an option for womb biospy/hysteroscopy? Cervical anaesthetic doesn't work on the womb. Thousands in agony.

14. When will women be given honest information beforgiving consent for outpatients gynaecology Hysteroscopy

15. The rcog has produced patient info and guidelines for hysteroscopy which aren't being used by many trusts. This means women aren't screened for likelihood of pain or offered GA etc. 25% suffer severe pain. What is Nadine Dorries going to do to ensure these guidelines and patient info is used?

Answer: Firstly, may I start by saying I am truly sorry to hear of the terrible pain that women have endured as a result of the hysteroscopy procedure. I understand that whilst it is a commonly performed investigation, and most women are able to have the procedure in an outpatient setting without local anaesthesia, it can be associated with significant pain for some women. You may be aware that I took part in a debate on this issue with Lyn Brown MP on 24th September, where I thanked Lyn and the Campaign Against Painful Hysteroscopy (CAPH) for their ongoing work on this issue. I also responded to a letter from the Campaign Against Painful Hysteroscopy on 17th December 2020.

With all invasive medical procedures, the Government agree that it is essential for patients to be given sufficient and accurate information so they can make an informed decision about what is best for them. The decision should be based on women's wishes, as well as clinical assessment. That is why the Government strongly supports the recommendation by NHS England and NHS Improvement (NHSE/I) to provide all patients in advance with the Royal College of Obstetricians and Gynaecologists (RCOG) patient information leaflet. This leaflet assists with obtaining informed consent for the procedure and contains helpful information for patients. It explains what the procedure is and what is involved, what patients should do beforehand, the questions they should ask healthcare professionals, risks and alternatives, aftereffects, and what will happen following the procedure.

In addition to this, The British Society for Gynaecological Endoscopy have also published a statement on RCOG's website in 2018 outlining that it is important that women are offered, from the outset and as part of the consent process, the choice of having the hysteroscopy procedure performed as a day case procedure under general or regional anaesthetic. The RCOG patient information leaflet also recommends that patients take pain relief 1–2 hours before appointments to help manage any pain. The leaflet advises that women can choose to have hysteroscopy as a day case procedure under general or spinal anaesthetic, which might be considered if women suffer from feeling faint during periods because of pain, or if they have experienced severe pain during a previous vaginal examination or cervical smear. Women are advised that the procedure can be stopped at any time.

To perform a hysteroscopy, all clinicians are trained as part of the RCOG Advanced Skills Training Modules (ASTMs). Moreover, during any industry sponsored training, it is required that all speakers delivering the training should declare conflicts of interest in order to be as transparent as possible.

NHSE/I are responsible for the design of the National Tariff. Hysteroscopy procedures are currently included in the day case best practice tariff (BPT). NHSE/I are currently planning to propose the removal of the day case BPT in the 2021/22 National Tariff. Additionally, NHSE/I propose an accelerated shift towards the use of aligned incentive payment approaches within the 2021/22 national tariff. The aligned incentive approach would not differentiate between in-patient and out-patient procedures and, as such, the out-patient procedure's BPT would no longer be necessary. NHSE/I have published the 2020 national tariff engagement document which lays out NHSE/I's initial proposals for the 2021-22 national tariff and will be followed by a statutory consultation expected in the next few months.

If women feel adequate care has not been provided during a hysteroscopy procedure, they have the right to make a complaint about any aspect of their NHS care, treatment or service. More information on how to make a complaint about NHS services is available online at https://www.nhs.uk/using-the-nhs/about-the-nhs/how-to-complain-to-the-nhs/. Additionally, if anyone has felt they have not been given adequate care by a medical professional during a hysteroscopy, they can raise their concerns with the General Medical Council (GMC) if they have not already done so. Details on the type of concerns the GMC can investigate, how to raise a concern, and the actions it can take to protect public safety and confidence in doctors can be found at www.gmc-uk.org/concerns.

With regards to the IMMDS Review patient reference group, I cannot comment on whether a representative from the Campaign Against Painful Hysteroscopy will be selected. DHSC has appointed Traverse, through an open and competitive tender process, to establish and facilitate the Patient Reference Group. Traverse are leading the recruitment process for group members and to ensure the process is fair, they will use a standardised scoring process to review applications and select candidates who demonstrate the appropriate skills and experience for the role, as outlined in the role description. This includes experience of, or an understanding of, the IMMDS Review, and it should be noted that hysteroscopy was not included in the remit of the Review.

The information given above and my written response to the CAPH in December outlines the Government's current position in relation to hysteroscopy. As there is little else I can say on the topic at the moment, scheduling a meeting at this time may not result in productive conversation.