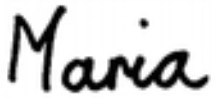
ALL-PARTY PARLIAMENTARY GROUP ON SURGICAL MESH

Maria Caulfield MP
Minister for Mental Health and Women's Health Strategy
Department of Health and Social Care
Ministerial Correspondence and Public Enquiries Unit
39 Victoria Street
London
SW1H 0EU

by email 19 January 2023

Dear 

On behalf of the All-Party Parliamentary Group on Surgical Mesh, may we offer our congratulations on your appointment as the Minister for Mental Health and Women's Health Strategy. With the recent publication of the Women's Health Strategy there is now a road map for improving women's treatment and experience of health provision in England and the Group wishes you every success.

We would like to raise a number of issues surrounding the treatment of those injured by mesh implantation surgery. Some of these remain outstanding from our communication to you of 23 December 2021, as Minister for Patient Safety and Primary Care.

Mesh removal centres

It is our understanding that the experience of patients varies greatly across the centres, and it has been described as a postcode lottery in terms of service delivery and wait times by patient groups. We are aware of waits of more than four years and reports of partial removals and poor aftercare. We are also aware that some patients have been told they have had "full removal" when this was not the case. In one example, only 2mm had actually been removed.

While we welcome patient choice of centre, in the absence of any financial support for travel, accommodation and loss of income then this choice is simply unavailable to many.

The situation in Northern Ireland is particularly concerning. There is still no specialist removal centre. Patients have to fly over to the UK and short-notice cancellations are

common. This is causing acute mental health problems to be added to the physical suffering. Even a trans labial scan currently requires a four year wait.

There is no mesh removal centre in Wales and we continue to receive reports that Bristol, the nearest centre for those in south Wales, is refusing to take NHS referrals from outside its area. Written Parliamentary Question (WPQ) 41014 on this subject received the answer:

An assessment of compliance [of the Bristol centre] *will be made through the quality surveillance programme and associated peer review in due course*

Rectopexy mesh removal is currently only available in London.

There is no standardized recording of removal outcomes across the centres. The situation has been described as "chaotic." This is particularly concerning as it echoes the circumstances surrounding the original implants. Without systematic, consistent recording and sharing of surgery outcomes over a sustained period we risk repeating the same situation.

The Department's answer to WPQ 13208 stated

NHS Digital has commenced work with patient groups and clinicians to develop a collection tool to capture patient reported outcome measures (PROMS) from patients as part of the Pelvic Floor Registry implementation. The interim PROMs infrastructure will be flexible enough to adapt to future academically approved questions, following research, to finalise a validated PROM for Pelvic Floor and related procedures. Outcomes captured by this interim PROM are anticipated to be used in conjunction with data that has already been collected by clinicians, which provides wider context.

However, we remain unaware of either an interim or finalised PROM.

Surgeons and recording of outcomes

Understandably, many women do not want to be operated on by the surgeon responsible for their original implant. Many have had negative experiences with these surgeons in their efforts to have their suffering recognized and treated.

One of the concerns highlighted in the Independent Medicines and Medical Devices Safety Review (IMMDSR) was the relationship of surgeons and the manufacturers of the devices they were recommending and implanting. It is our understanding that the Department has made no requirement for removal centres to require any such disclosures on behalf of their surgeons and is content to leave the matter to individual centres.

There appears to be an assumption that mesh implant surgeons will automatically be skilled in removal. However, the two procedures are quite different. We are reliably informed that the complex removal procedure is not one that a general surgeon can simply "pick up." There is currently a lack of specific training for surgeons and, as borne out by the length of time sufferers are waiting for treatment, a lack of surgeons.

The absence of standardized recording of outcomes and specific surgeon training means that the victims of mesh face the prospect of being used as test subjects once again.

Retrospective audit

We have very serious concerns regarding the recent audit of pelvic floor surgery undertaken by NHS Digital. In an answer to WPQ 103061 on this subject, the Department originally stated that along with Hospital Episode Statistics (HES) data, "*other data using the identified National Health Service cohort of patients and the longitudinal record to observe outcomes where possible."* Following a further WPQ (110813) requesting details of the "other" data sources it was revealed that in fact only HES data was used. This is wholly unsatisfactory. According to Kath Sansom admin of the Sling the Mesh Facebook group, every single person on the group was recorded as a success by the criteria used to collect the HES data. Any woman who went to a different hospital for removal or other treatment (as so many did, having no confidence in their original surgeon) will not be recorded, nor will any who were treated in the private sector. Any treatment in Primary Care will not be in the HES data. This audit is a long way from what was recommended in IMMDSR:

If possible, this prospective database 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. A retrospective follow-up of all women who underwent mesh surgery in one year (2010 has been suggested), or a representative sample from a range of Trusts could be attempted. p165

We note that in the case of Ian Paterson, every woman who underwent surgery was traced and contacted. We also find it significant that the Department assumed that data beyond HES was being collated. Without the inclusion of other data, this audit fails to respect the wishes of Baroness Cumberlege's report, fails to honour the suffering of those women whose voices went unheard for so many years, and is scientifically worthless.

Redress

Recommended by the IMMDSR Report was a Redress Agency and immediate payments to mesh victims. As already illustrated, the choice of mesh removal centre comes with a

financial cost. Further, extended waits of years for treatment adds to the costs of everyday living with the disability caused by mesh injury, to say nothing of the toll on mental health. The suggestion that the legal route to compensation is sufficient is simply untenable. There are many obstacles, not least the requirement that a claim must be submitted within three years of obtaining the knowledge that mesh surgery was the cause of injury. The IMMDSR Report is crystal clear that these victims were dismissed, obstructed and in many cases simply lied to for years.

Asks

- The absence of a mesh removal centre, and the suffering of the mesh injured in Northern Ireland be urgently addressed
- Training of surgeons in mesh removal
- Establish a standardised recording of removal outcomes across all mesh removal centres as a matter of urgency
- An update on the progress of the Medical Device Information System with respect to mesh
- A retrospective follow-up of all women who underwent mesh surgery in a particular year
- A 'Sunshine Payment Act' as recommended by the IMMDSR Report; we believe the proposed "local" declarations by practitioners is an inadequate response to the Report recommendation.
- Immediate redress for the victims of mesh surgery and the establishment of a Redress Agency as per the IMMDSR Recommendations

We hope that you find this letter helpful and we look forward to your reply.

Yours sincerely,

Emma Hardy MP
Hull West and Hessle
Co-Chair APPG Surgical Mesh

Alec Shelbrooke MP
Elmet and Rothwell
Co-Chair APPG Surgical Mesh

Cc: Baroness Julia Cumberlege, CBE DL