TPFS Response to IMMDS

The Pelvic Floor Society (TPFS) welcomes the publication of the ***Independent Medicines and Medical Devices Safety (IMMDS)*** review report ***"First Do No Harm",*** published on 8th July 2020.

This comprehensive document reports on the findings of an independent team's review into how the health system responds to reports from patients about harmful side effects from medicines and medical devices. The team was chaired by Baroness Julia Cumberlege CBE DL, assisted by Sir Cyril Chantler and Simon Whale and looked at the use of the two medicines and one surgical device, surgical mesh for the treatment of stress urinary incontinence (SUI) and Pelvic Organ Prolapse (POP) surgery.

With regards to use of surgical mesh, the "*First Do No Harm"* report said it had been unable to identify how many women had been treated for stress urinary incontinence (SUI) and the repair of pelvic organ prolapse (POP) using polypropylene mesh because full data does not exist. In addition the report said the healthcare system did not know how many women had been successfully treated and what proportion of them had been left with permanent physical and/or psychological injury.

"We have found that the healthcare system – in which I include the NHS, private providers, the regulators and professional bodies, pharmaceutical and device manufacturers, and policymakers – is disjointed, siloed, unresponsive and defensive. It does not adequately recognise that patients are its raison d'etre. It has failed to listen to their concerns and when, belatedly, it has decided to act it has too often moved glacially. Indeed, over these two years we have found ourselves in the position of recommending, encouraging and urging the system to take action that should have been taken long ago,' said the report".

Nine recommendations were made within the *"First Do No Harm"* report**.**

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.*

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.*

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.*

TPFS Response to IMMDS

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

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.*

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.*

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 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*

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 pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions and individual clinicians.*

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

The Pelvic Floor Society wish to thank the IMMDS review team for their hard work over the last two years, specifically regarding the recommendations for the use of mesh in corrective surgery for POP. As a society, we are fully supportive of the report's findings and recommendations.

The Pelvic Floor Society applauds the recommendation to appoint an independent Patient Safety Commissioner and is keen to engage and seek representation on the suggested task force that will establish a network of specialist mesh centres to provide comprehensive treatment of those patients affected by implanted mesh. We will continue to engage with the Department of Health & Social Care to provide a better service for patients who have come to harm as the result of the surgical implantation of mesh in the pelvis. We are committed to and fully support the commissioning of regional mesh complication centres to provide uniform access to appropriate service throughout the country.

We welcome the report's recommendation to create a robust, central patient-identifiable database for all devices and outcomes, an NHS-run mandatory reporting system. A central patient-identifiable database is vital to achieve a more joined up approach to recording and regulating the use of medical devices across the whole healthcare system to keep patients safe and to audit short and

long-term outcomes for patient safety. The database must also provide us with essential Mesh Patient Reported Outcomes Measures (PROMs) to allow meaningful comparisons between all surgical procedures for POP. We, as a society, also support the use of data collection to include all surgical treatments for POP (and SUI), to allow us to compare treatments and provide sufficient data to aid the process of fully informed consent when a patient is considering a range of potential treatment options for rectal and pelvic organ prolapse. We are committed to developing bespoke outcome data measures, working together with patient groups.

As a society, patient care must be at the centre of what we do. In line with NICE Guidelines (2019:ng123) we fully support the recommended *Action for Improvement* - patients should be offered conservative treatment and management measures from specialist pelvic floor physiotherapy or specialist nurse-led services before surgery is undertaken. Surgery should only follow exhaustion of non-surgical options and should be sanctioned after agreement by a multi-disciplinary team, where all treatment options should have been explored and discussed.

TPFS recognised early emerging concerns of the use of mesh in rectal prolapse surgery. Over the last 3-4 years, TPFS has developed a wealth of documentation to help support patients and enable them to make appropriate treatment choices. These include Patient Information Leaflets on Laparoscopic Ventral Mesh Rectopexy (LVMR) and the use of mesh in POP surgery. The leaflets (What is a Lap Ventral Rectopexy; Preparation and Recovery Ventral Mesh Rectopexy; What do I need to know about having a mesh?), an Enhanced Consent form and a Checklist for Consent for LVMR are all available for download from TPFS website.

We continue to encourage our members to input anonymised data onto the current TPFS Mesh registry until it is replaced. There are over 1200 patient episodes pertaining to LVMR that will provide important information regarding frequency of this operation and the complications and risks with them.

We will continue to work tirelessly on the behalf of our membership as we commit to improving outcomes for patients with pelvic floor disorders. As Dame Cumberlege states in her report, the healthcare system must ***'NEXT DO SOME GOOD'*** to support those patients who have had an adverse outcome from surgical procedures using implantable surgical mesh. We, as a society, will fully support and guide our members appropriately with regard to the implementation of the recommendations made in the IMMDS report.

TPFS

July 2020