British Hernia Society submission of 10 January 2024

PE1865/OOOO: Suspend all surgical mesh and fixation devices

Thank you for your request for comment from the British Hernia Society, on the above petition. We extend our empathy to all patients who have experienced pain or complications following hernia surgery. Patient safety and wellbeing should be the first priority for all surgical care. Unfortunately, the nature of surgery in general, not just groin hernia repair using mesh, carries an inherent risk of complications. As a Society we advocate that surgeons should always seek to assess this risk and discuss patients' individual clinical circumstances with them as a part of a thorough counselling and consenting process prior to deciding if surgery is appropriate and if they accept the risks vs the benefits.

The British Hernia Society **cannot** support a decision '***to suspend the use of all surgical mesh and fixation devices'*** for a period of time. This would be against the best scientific evidence and against the current guidelines published by the European Hernia Society. Mesh has been widely used for over thirty years to repair abdominal wall hernias and the best available evidence that we have, which includes systematic reviews, meta-analyses of randomized trials and large 'hernia' registries, shows that mesh implants are the most effective way to deal with these types of hernias and are safe. Nevertheless, we acknowledge that randomised trials do not always provide real-world data or in many cases long term data on the use of implants. We know some patients, who currently the data would suggest are still a minority, will suffer from complications of mesh use, like other implants, such as mesh infection and erosion with the need for explantation. This does not detract from the need to improve outcomes or to properly counsel patients prior to any surgery. However, a suspension would disadvantage the great majority of patients with hernias who also have significant health and quality of life issues.

Having said this we come from a standpoint that there needs to be improvements in patient outcomes and one of the factors here is medical implant regulation. The significant complications from transvaginal mesh procedures resulted in public reviews, including the Baroness

Cumberlege report, “First Do No Harm”. The report gives clear recommendations that are important and relevant to hernia surgery and address the way devices are approved, delivered, regulated and monitored. Subsequent changes in the regulation of medical devices, in Europe and the UK, has led to the pressing need for a registry for hernia surgery to satisfy the legal requirements for post-market surveillance of devices, research and the analysis of long-term outcome data, including patient-reported outcome measures. A registry captures details about the type of hernia, the surgery undertaken (open, laparoscopic or robotic), including whether implants are used (meshes and tacks by company, material, size and type) and tracks the results thereby providing outcome data.

The British Hernia Society has developed a registry over the last 3 years to permit large-scale, cost-effective embedded research, track outcomes across a lifetime, and, therefore, improve patient safety. Patient-reported outcome measures (PROMs) are key to understanding the true results of surgery and PROMs are collected intermittently over the lifetime of patients in the BHS Registry. We have worked with NHS England Supply Chain and GIRFT (Getting It Right First Time) regarding the implants that are currently available with the aim of guiding implant use based on this registry research in the future. The BHS Registry will allow the rapid objective assessment of new implants which is not possible at the moment. We feel that having this data is the only way to ensure we can improve outcomes for all our hernia patients by ensuring we provide the most appropriate surgery and implant for each individual patient. We believe a mandated and compulsory BHS Registry provides the best approach to allow the questions raised by this petition, and many others, to be answered.

The registry is currently undergoing a final snagging phase and will be rolled out nationally in 2024. Success of the registry is dependent on the quality of data entered into it. For real-world outcomes, more than 95% of all procedures must be captured. This means that *mandating* the registry for use in both public and private sectors is essential. The British Hernia Society asks the Scottish Government to work with us to enable this.