PE1865/WWWW: Suspend all surgical mesh and fixation devices

Minister for Public Health and Women's Health written submission, 21 March 2025

Thank you for your letter of 21 February concerning the above named petition. I am grateful to the Committee for its extended consideration of this petition during this session, and my officials have been grateful for the opportunity to meet with the petitioners to discuss the issues that are the focus of the petition.

Your letter, along with the petitioners, seeks assurance regarding the Scottish Government's plans for maintaining datasets related to surgical mesh and fixation devices, ensuring they remain as up-to-date, complete, and accurate as possible. The petitioners propose a further review.

The Scottish Government agrees with the objective of ensuring that evidence is as up to date as possible. We do consider that the independent review undertaken by the Scottish Health Technologies Group (SHTG) offers an accurate analysis of the most relevant and high-quality research evidence on the use of mesh for hernia repair. SHTG projects are based on thorough and systematic literature searches, carried out by evidence specialists. The reviews and meta-analyses included in the SHTG review represent the highest quality and most reliable type of evidence available for assessing clinical effectiveness and safety. Moreover, engagement with stakeholders and interested parties helps ensure that any additional studies are considered prior to publication of a SHTG review.

The evidence on hernia mesh published since 2021 aligns with the SHTG advice, both in terms of outcomes and patient follow-up. But I wish to underline that SHTG – and the Scottish Government – remain committed to considering new evidence should it become available.

The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for overseeing the safety and regulation of medical devices in the UK, including implantable devices, and they keep the safety of all medicines and medical devices under continual review. Having looked at all the available sources of information, including scientific papers and clinical trials, the MHRA has confirmed that their position is that there is currently no evidence for them to take further regulatory action with regards to surgical mesh. They are however keeping this issue under review and will continue to work with colleagues across the health sector to monitor and examine evidence as it becomes available.

The National Institute for Health and Care Excellence (NICE) regularly reviews evidence to update its clinical guidance and some of their products include hernia repair: Products - Hernia | Topic | NICE. For anyone seeking to influence clinical guidance, individuals can submit evidence via the NICE Contact Us portal (https://www.nice.org.uk/get-involved/contact-us). Additionally, in Scotland, the Scottish Intercollegiate Guidelines Network (SIGN) is part of the Evidence Directorate of Healthcare Improvement Scotland and collaborates with health and social care professionals, patient organisations and individuals to produce evidence-

based guidelines for NHS Scotland. Any group or individual can propose a guideline topic or request that the research is considered in Scottish clinical guidelines.

Patient safety is of paramount importance for NHS Scotland and the Scottish Government is committed to improving and utilising medical device data at national level and maximising its use to improve patient safety. With this aim in mind, a number of programmes and initiatives to provide up-to-date and comprehensive data for medical devices, including pelvic and hernia mesh, are underway. These include:

The Scottish Pelvic Floor Registry Audit Programme (SPFRAP), led by Public Health Scotland (PHS), being established in NHS Scotland, to enable an evidence and data-based approach to improving the provision of pelvic health services for those seeking treatment for pelvic organ prolapse, stress urinary incontinence and complications from previous pelvic mesh surgery across NHS Boards, primary care and independent providers.

The data collected by SPFRAP will also provide the required data for the UK Pelvic Organ Prolapse and Stress Urinary Incontinence registry currently being developed by the Department of Health and Social Care (DHSC). The UK registry aims to ensure that appropriate clinical vigilance data is collected, surgical outliers can be identified and comparative performance and outcomes are routinely available.

With specific regards to hernia mesh data, **the British Hernia Society (BHS) has established the British Hernia Society Registry**, which is now live. This registry aims to collect data on elective and emergency hernia repairs across the UK, including data on complications and patient-reported outcomes. This will inform guidelines and best practices for surgeons and healthcare providers. Scottish Government officials will observe the registry with interest and consider whether it provides a suitable registry solution.

Furthermore, NHS Boards are currently implementing the **NHS Scotland Scan for Safety Programme**, led by NHS National Services Scotland (NSS), in partnership with NHS Boards, to provide the rapid electronic traceability of implantable devices. Using Point of Care (Poc) scanning technology, implantable devices will be linked to patient identification allowing for the rapid electronic search to trace devices in the event of a safety recall and will improve our future knowledge of real world outcomes for medical devices.

Every Health Board has a formal complaints procedure and patients must not hesitate to make a complaint if they are in any way unhappy with their treatment. It is through feedback of this nature that the Health Board can identify any issues and take steps to make improvements in the future. If unhappy with the Health Board's final decision, patients can ask the Scottish Public Services Ombudsman (SPSO) to review their complaint. Guidance on making a complaint can be found at Complain about an NHS service - mygov.scot. For help and advice with complaints, contact your local Patient Advice & Support Service (PASS). The service is free, independent and confidential.

I hope this is helpful.

Yours sincerely,

Jenni Minto MSP