Minister for Public Health, Women's Health and Sport submission of 28 October 2022

PE1865/KKKK: Suspend all surgical mesh and fixation devices

Thank you for your letter dated 30 September and I write here to address the points you raise. Before doing so, however, let me say that I did take careful note of the report of the committee's meeting on 28 September. I noted in particular important points made and concerns raised in relation to informed consent, and in that connection, reports of instances where clinicians were said to have not communicated in the empathetic way that I think all would reasonably expect. These issues, which are of course partly cultural ones, have and continue to be a focus for the Government and for the NHS in Scotland.

I take these concerns very seriously and as you are aware, both informed consent and effective communication are key features in Realistic Medicine, which the Scottish Government champions. The Chief Medical Officer has written to Health Board Medical Directors on this and it will be drawn to their attention again. Also, as I reported to the Committee in June, work is ongoing to empower patients to better engage in meaningful discussions with clinicians and the promotion of "BRAN" (benefits, risks, alternatives and the option of doing nothing) as a simple aide-memoire is an example.

What scope there is for Scotland to independently test devices, in addition to the work done by MHRA

As you know, the regulation of medical devices is reserved to the UK Government. The MHRA is currently reforming medical device regulation in the UK and recently ran a UK-wide consultation on proposed changes.

The MHRA proposals intend to increase the classification of surgical mesh implants from a Class IIb device to a Class III device (generally regarded as high risk devices). Devices are classified according to guidance set out by the MHRA and the certification process is different for each class of device. This change will involve a greater level of

scrutiny on surgical mesh in both pre- and post-market assessment and surveillance and require manufacturers to regularly provide clinical evidence of their safety as part of the recertification process required for high risk devices.

The UK Government has now published the response to the public consultation: Consultation on the future regulation of medical devices in the United Kingdom - GOV.UK (www.gov.uk)

All medical products that are procured by NHS Scotland must meet the requirements of the UK medical devices regulations and be appropriately CE marked. This is the minimum requirement for all medical devices.

With regard to implants, due to their certification level, there are specific compliance requirements on evidence and control as well as post-market surveillance. This aspect is audited by the independent approval organisation that will award the CE marking certificate. More information is available online at: https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#overview

What discussions the Scottish Government has had, or plan to have, with Shouldice Hospital, or similar European centres, to explore opportunities for sharing expertise in natural tissue repair, and what the outcomes of those discussions have been

The Scottish Government commissioned two reviews by the Scottish Health Technologies Group (SHTG) into the use of mesh in hernia repair. The subsequent reports were shared with your Committee and the findings were discussed during the evidence sessions I attended. Based on comparative outcome data derived from peer-reviewed and published studies, including those involving non-mesh surgery, SHTG concluded that "…evidence supports the continued availability of surgical mesh as an option for elective repair of primary ventral hernias, incisional hernias and primary inguinal hernias in adults in Scotland". This notwithstanding, SHTG also concluded that "Patient preference may be for a non-mesh (suture) hernia repair and access to alternative hernia management options should be available to accommodate this". In this context, the report from Shouldice Hospital is helpful and the Scottish Government has drawn it to the attention of SHTG, relevant Royal Colleges, Specialist Associations and the Scottish Association of Medical Directors (SAMD).

Furthermore, and to encourage provision of patient choice where this is clinically appropriate, the Scottish Government has asked SAMD to report on the availability of non-mesh surgery in individual Health Board areas and to highlight any skills or training gaps. The outcome of this exercise is awaited and further discussion will take place. The Scottish Government is mindful however that this is a clinical issue and appropriate boundaries need to be observed.

What progress has been made on establishing the medical information system to help track the outcomes of mesh and non-mesh hernia repair and identify opportunities for improvement;

With regard to the UK Medical Devices Information System (MDIS), the four UK nations are working collaboratively to develop a model that will improve knowledge of outcomes for medical devices. NHS England is leading the development of technical options, and these discussions continue.

Further to this, the Scottish Government is taking forward improvements in the recording of procedures and implanted devices. This is with a view to improving traceability, allowing rapid and efficient recall of devices in the event of an issue with a particular procedure or device, and also to improving our knowledge of clinical outcomes.

Four Health Boards will shortly begin a pilot of a UK-wide Pelvic Floor Registry, which will allow the recording of all treatments for pelvic organ prolapse and stress urinary incontinence, as well as mesh removal procedures. Furthermore, an NHS Scotland Scan for Safety Programme is being developed: all medical devices are in scope, but with a primary focus, until 2025, on high risk implantable devices used in acute healthcare settings. This will include mesh, joint replacements and cardiac devices.

The British Hernia Society has also been working on a hernia specific registry and are engaging with NHS Digital on the overlaps between this and the MDIS.

What further consideration has been given to extending the scope of the existing Complex Mesh Surgical Service or establishing a specialised unit or centre of expertise for hernia repair

The National Complex Pelvic Mesh Service in NHS Greater Glasgow and Clyde has been established specifically to provide expertise in the management of complications associated with the use of mesh in female urogenital surgery and in particular following transvaginal mesh insertion. A multi-disciplinary team (MDT) of clinicians has been brought together with this focus and it is for that reason that they do not accept referrals for abdominal and groin hernia mesh problems.

With regard to establishing a similar national centre for hernia mesh complications and removal, at present the Scottish Government does not believe this is required although it will be important to learn and share relevant experience from the centre in Glasgow. Within each Health Board there is expertise in hernia repair with more specialist interest and skills being developed by some surgeons. The Scottish Government has encouraged the establishment of Health Board clinical groups and networks so that complex cases can be discussed and expertise and experience shared across Scotland. Involvement of clinicians with non-surgical skills can be recruited as required. This has already been discussed with SAMD and further conversations will follow.

Whether the Scottish Government plans to commission an independent review of all mesh devices.

There are no plans to undertake an independent review of all surgical mesh. The Scottish Government has brought forward a substantial programme of work on this issue, including reports from the Health and Social Care Alliance and SHTG, and we expect the Transvaginal Mesh Case Record Review to conclude later this year. In addition to this, the Scottish Government accepted all the recommendations made by Baroness Cumberlege in her Independent Medicines and Medical Devices Review (IMMDS), where these were within Scottish powers, and committed to working with the UK on the matters which are reserved. It is unclear what an additional review would add to this but I hope our commitment to improving services for all harmed by mesh is clear.