

RCOG and BSUG welcome publication of the Independent Medicines and Medical Devices Safety Review

The Independent Medicines and Medical Devices Safety Review, chaired by Baroness Julia Cumberlege, has today published its report "[First Do No Harm](#)", focusing on three medical interventions: primodos, sodium valproate and pelvic mesh.

In a two-year investigation, the review team has looked at how the healthcare system in England responds to reports from patients about harmful side effects from medicines and medical devices.

The report sets out nine recommendations to bring much-needed help and support to those who have suffered as a result of these interventions, and to reduce the risk of avoidable harm from medicines and medical devices in the future.

The Royal College of Obstetricians and Gynaecologists and the British Society of Urogynaecology contributed to the review by submitting written evidence and taking part in oral briefing sessions with the review panel.

Dr Edward Morris, President of the Royal College of Obstetricians and Gynaecologists, said:

"We welcome the publication of this report from the Independent Medicines and Medical Devices Review and the wide ranging recommendations put forward by the review team. There is clearly urgent reform needed across the healthcare system to ensure we learn from these past mistakes and we will be encouraging all our members to read the report in full.

"It is completely unacceptable that so many women and their families have suffered avoidable harm from these medical interventions that were meant to help them. Across the health system, it is imperative that we continue our work towards developing high quality and safe services that place women at the centre of their care.

"To achieve this, we will review the report's recommendations in detail, as part of our ongoing efforts to champion the very best in women's health. We will issue a detailed response on how we can take forward these recommendations in the near future, aligned with the wider healthcare system. We support the setting up of a task force to implement the Review's recommendations.

"I would like to thank all the women and their families who have spoken to the review about their experiences. It is only by listening to the women we care for that we can learn about where improvements are needed to provide only the safest and highest quality of healthcare."

Dr Swati Jha, Chair of The British Society of Urogynaecology, said:

"The Independent Medicines and Medical Devices Safety Review has provided an important opportunity for all key partners across the health system to reflect on how we can do better to improve healthcare services for women.

"For us, the priority has always been to provide the safest treatments for stress urinary incontinence and pelvic organ prolapse. The recommendation in the review to establish a mandatory database must be taken forward urgently using the knowledge and experience BSUG have gathered over the past 10 years.

"BSUG have been calling for mandatory database entry for years and we are very pleased that this recommendation has been made, and it should now be implemented. We have also put into place a formal training scheme for non-mesh continence procedures to ensure patient safety going forward.

“For women with complications, it is vital that they are listened to, and provided with high quality care and support. We take every complication caused by mesh implants very seriously and we know, that for women affected by this, it can have a devastating effect on their lives.

“We continue to work closely with NHS England and other organisations to ensure our health services are fully responsive to women’s needs now and in the future.”

Shaista Gohir, RCOG Women’s Voices Lead, said:

“This independent review yet again highlights the importance of women’s voices. I particularly welcome the recommendation of a Patient Safety Commissioner as this will enable an appointed individual to use legal powers to join the dots in the healthcare system more quickly and hold to account those responsible for women’s health care.

“All women must receive a high standard of care which can only be achieved if women’s experiences are heard - their concerns, complaints and symptoms must not be dismissed and they should not have to wait years before they are taken seriously.

“Women’s voices are given high importance at the RCOG as they are used to influence and inform the work of the College. In my role as the Women’s Voices Lead, I will work with the RCOG to continue listening to what women say and carefully consider the findings and the recommendations in the report.”

Ends

Note to editors

For media enquiries, please contact the RCOG press office on +44 (0)20 7045 6773 / pressoffice@rcog.org.uk

The RCOG has developed [online resource](#) on mesh for healthcare professionals and women.

BSUG has developed and is providing a [mentorship scheme](#) for training of consultants in the field of urogynaecology. This is to the same standard and as rigorous as the training required for doctors in training.

BSUG continues to encourage doctors to record all cases on [its database](#) and report all complications to the MHRA. The BSUG database has a direct link to the MHRA reporting system.

BSUG has developed decision aids to help women and healthcare professionals review treatment options for incontinence and prolapse, which support recommendations from NICE.

A period of high vigilance restriction regarding vaginal mesh is currently in place in England and Scotland. Read the [College’s safety alert](#) for more information.

RCOG/BSUG support NICE [clinical guidance](#) on treatments for the management of stress urinary incontinence and pelvic floor prolapse.