

BSUG Actions following the Recommendations of the IMMDS Review

Following the publication of the IMMDS Report on the 8th July, the British Society of Urogynaecology have had an opportunity to deliberate and take steps to address the recommendations. There are obviously some recommendations that are outwith our remit but we would like share what we are doing. We wish to make this an open and transparent process and ensure patients and public bodies have access to any actions taken. By doing so we hope to demonstrate our commitment to ensuring that all recommendations are met in a timely manner to the satisfaction of patients who have suffered harm from the use of mesh.

| Recommendation | Actions taken/Ongoing |
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| Recommendation 1: The Government should immediately issue a fulsome apology on behalf of the healthcare system to the families affected by pelvic mesh. | We made an apology to women and families who have been harmed by the use of pelvic mesh following the release of the report (https://bsug.org.uk/). We sincerely regret not having done so sooner. |
| Recommendation 2: The appointment of a Patient Safety Commissioner who would be an independent public leader with a statutory responsibility. | <p>Though this is outwith the remit of BSUG, we are in the process of advertising and appointing a team of patient representatives to the BSUG. One of them will represent the patient group on the BSUG Committee. We hope this will go some way to giving a patient voice to decisions made by the organisation.</p> <p>Following the appointment of a Patient Safety Commissioner, BSUG will work with them to assist in their role should this be required.</p> |
| 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. | This is outwith the remit of BSUG, but we would be willing to assist and advise the Redress Agency when it becomes functional. |
| Recommendation 4: Separate schemes should be set up for each intervention to meet the cost of providing additional care and support to those who have experienced avoidable harm and are eligible to claim. | This is out with the remit of BSUG. We would be keen to assist with any alternative resolution initiatives suggested and proposed by the DHSC. We continue to assist litigation agencies to provide information when requested in relation to |

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| | <p>claims and provision of archived copies of contemporaneous information leaflets.</p> |
| <p>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.</p> | <p>The BSUG is working with Specialist commissioning in the setup of Specialist centres for Mesh removal services. We are in consultation with them to ensure that centres are distributed such that patients from all geographical areas have access. We also recognise that patient consent to linkage of data on registers and other healthcare systems is required. We continue to provide advice and are contributing actively to the service specification for this workstream. We are keen to have a system of appraisal/ accreditation for the centres annually to ensure all centres meet high standards to ensure patient safety.</p> <p>We are working with the NHS England Mesh Oversight group and Specialist Commissioning to consider pathways for the management of Complex urogynaecology conditions to ensure these are clearly defined.</p> <p>We are working with the Maternity Transformation Programme in an advisory role and provide input into their various workstreams. These are aimed at preventative strategies for managing pelvic floor problems with the objective of improving pelvic floor health.</p> |
| <p>Recommendation 6: The Medicines and Healthcare products Regulatory Agency (MHRA) needs substantial revision particularly in relation to adverse event reporting and medical device regulation.</p> | <p>This recommendation is for the MHRA. However, the BSUG have been encouraging its members to report all complication to the MHRA since 2012. The BSUG have significant experience of submitting data to the MHRA and a link was set up from the BSUG database to submit data directly to the MHRA through the Yellow Card system in 2017. We are aware of the pitfalls associated with this process and have made suggestions to NHS Digital of how this can be achieved and how to make this data submission and linkage meaningful.</p> |

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| <p>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.</p> | <p>BSUG are working with NHS England and its Mesh oversight group and Mesh Registry subgroup to facilitate the set up and development of the Pelvic Floor Registry (PFR).</p> <p>We have regular meetings with the NHS Digital team to provide clinical input into the data items that will be recorded. The Mesh oversight group have liaised with patient groups so that we have now captured a list of all reported problems that may have a link to the use of mesh. This will enable these complications to be captured by the registry with time.</p> <p>We are very keen that data collection in the PFR is:</p> <ul style="list-style-type: none"> -independent of clinicians to avoid any bias -allows for comparison with other non-mesh procedures -allows for data collection with meaningful PROMs which patients feel are useful, however this needs to be submitted by patients directly to the registry independent of clinicians. <p>BSUG recognised the need for urgent data analysis to establish 2 keys issues:</p> <ol style="list-style-type: none"> i) the association of Autoimmune diseases with vaginal mesh & ii) the harm that can ensue following any continence procedure compared to mesh related continence procedures. <p>Since it will be a while before this data can be collected through the PFR, we have undertaken work with the London School of Hygiene and Tropical Medicine to analyse HES (Hospital Episode Statistics) data to answer these questions. These retrospective audits have been ongoing for the past 7 months are now nearing completion and will soon be in medical</p> |
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| | <p>literature. They will serve to address the above questions.</p> <p>Once the PFR is up and running, the plan is to conduct a retrospective audit of all mesh devices conducted in 2010. BSUG will assist and facilitate this process.</p> |
| <p>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 the pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions and individual clinicians.</p> | <p>BSUG have now published their Declarations of interests on our website for all committee chairs and Executive committee members (https://bsug.org.uk/pages/about/conflict-of-interest/147).</p> <p>We will be encouraging all our members to do the same through their own employing organisations or through the BSUG.</p> |
| <p>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.</p> | <p>This is outwith the remit of BSUG, but by engaging with all the Government organisations as listed above and proactively acting and responding to the recommendations of the IMMDS report we hope to start to regain the trust of those patients we have lost over the years.</p> |

Other steps taken in response to the IMMDS Review and Report:

1. BSUG Mentorship scheme (<https://bsug.org.uk/pages/information/nonmesh-continance-surgery-mentorship-scheme/123>) was set up to support clinicians offering Non-Mesh Continance surgery to ensure they were adequately trained in providing this.
2. Appraisal tool for Clinicians undertaking Pelvic floor surgery (<https://bsug.org.uk/pages/useful-documents/143>) have been developed to make it easier for them to demonstrate they comply with the governance checklist in place to protect patient safety.

3. Changes to the Patient Site of the BSUG Website to make it more informative (Ongoing development).
4. We will issue a statement annually of the funding we receive from pharmaceutical companies (<https://bsug.org.uk/pages/about/sponsorship-for-2019/148>).
5. We are planning to incorporate training for obtaining informed consent to clinicians in forthcoming BSUG Meetings/ workshops.
6. We are working with the other Specialist Societies and NICE to develop Patient information leaflets and Patient Decision Aids for mesh removal.
7. We are working with the RCOG to make a case for Credentialing of Mesh Removal surgeons with the GMC. This will ensure all surgeons undertaking this work are adequately trained and have the expertise to offer these services.

on behalf of the BSUG Committee

Swati Jha
Chair, BSUG

30th October, 2020