

The Baroness Cumberlege Report: "First Do No Harm"

You may have read about the report entitled "First Do No Harm" that appeared this June. This was a report of a Review carried out for the body in charge of Medicines and Medical Devices. (The Report is sometimes referred to by the name of its chair, Baroness Cumberlege.) Its relevance to the SIMS trial is that one of the medical procedures considered was the use of mesh implants in the treatment of prolapse or stress urinary incontinence. (The other 2 were hormone pregnancy tests and the impact of taking sodium valproate during pregnancy.)

There were concerns expressed in the review with regards the use of mesh. These included lack of sufficient information for patients before they accepted treatment, not high enough standards of training for some clinicians, and lack of information on long-term outcomes. The systems in place for the SIMS trial have ensured that all patients were given detailed information, including the opportunity to ask questions: we hope you feel that was the case. All the surgeons involved in the trial had been carefully assessed regarding their competence in the procedures. Finally, a major task of the SIMS trial is to produce information on long-term outcomes, which will be useful to any future patients.

Recommendations in the report of particular relevance are that there should be specialist centres for mesh treatments; and a national database of treatments carried out, including Patient Reported Outcomes. The NHS is already working on setting up centres and the work of the SIMS trial will feed into the database once established. Another recommendation is for more patient involvement in the development of new devices: the SIMS team welcomes this recommendation as well as the others.

If you want to read the full report, it can be found at: www.immdsreview.org.uk/Report.html. The first chapter contains a useful summary of the findings.

We have added links to more detailed information about this on the SIMS Study website - w3.abdn.ac.uk/hsru/SIMS. If you don't have internet access and would like this further information in print please contact the trial office (contact details below).

If you have any questions about your ongoing care please contact the consultant in charge of your care at the hospital where you had your operation. If you have any further questions please don't hesitate to contact either the study trial office on 01224 438180, email - SIMS@abdn.ac.uk