International Symposium–Meet the Experts:
1. Primary Care of Women
Up-to-date practice in general Gynecology/gynecologic care

1) Female Prolapse Surgery after FDA—an Update

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Around 13,000 vaginal tape implants are used every year to treat women suffering from stress urinary incontinence, and 1,500 mesh implants for women with pelvic organ prolapse. These can be very distressing conditions and, for most women, the development of these new surgical techniques has resulted in a welcome improvement in their quality of life.

A small percentage of women have suffered significant side effects after this type of surgery such as pain and sexual dysfunction. For vaginal tapes for stress incontinence the adverse rates are very low, typically affecting between 150 (one per cent) and 500 (three per cent) women each year.

For vaginal meshes used in prolapse surgery, adverse rates corresponding to about 200 (15 per cent) procedures a year have been found in some studies, but these figures are difficult to interpret because a significant number of patients suffered problems before surgery.

Now the Department of Health, clinical groups and the MHRA are working together to make sure that surgeons have all the necessary guidance and support to carry out these operations as safely and effectively as possible, and that women feel reassured before making decisions about undergoing surgery. These measures will include developing proposals for a registry for implanted vaginal tapes and meshes to help surgeons to compare the outcomes of their treatment, building on the voluntary registries already established by the professional associations.

For the vast majority of women, mesh and tape implants are a safe and effective operation, but as with all surgery, there is an element of risk.

Synthetic meshes are used in surgery to treat pelvic organ prolapse. This is a relatively new technique and DH is funding an ongoing trial (the PROSPECT trial) comparing surgery with and without use of meshes. About 1,500 such operations are carried out in the UK each year.

The Department of Health, NHS Commissioning Board, MHRA, and the relevant professional organisations have agreed an outline action plan to address the issues raised by the report. The key elements are:

To develop proposals for a single registry of vaginal implants, building on the existing registries main-
tained by the professional associations;

To develop and issue professional guidance for surgery using vaginal meshes, complementing existing NICE guidance, on aspects such as selection of patients, choice of device, and processes for informed patient consent;

To develop and issue guidance to commissioners to enable them to commission services from providers which maintain high standards of training and clinical audit;

To develop and issue professional guidance on those centres competent to carry out surgery for women with recurrent problems from incontinence or prolapse, or women needing further surgery as a result of complications.