FSRH STATEMENT: RESPONSE TO THE FDA REVIEW OF ESSURE
October 2015

Essure® is a form of female sterilisation which involves the hysteroscopic insertion of flexible micro-inserts into the proximal section of the fallopian tubes and is undertaken without general anaesthesia.[1]

An advisory committee of the Food and Drug Administration (FDA) in the United States heard evidence on 24/9/2015 relating to reports of adverse events resulting from use of Essure. The Obstetrics and Gynecology Devices Panel of the FDA report that they reviewed available safety and effectiveness data and heard evidence from patients and their representatives, clinicians and professional bodies.[2]

Essure-related events considered included persistent pain, uterine or fallopian tube perforation, migration of the device, abnormal or irregular bleeding, allergy or hypersensitivity reaction, pregnancy and device removal. The panel discussed support for informed decision-making by patients; the importance of access to confirmation tests and to clinicians trained in removal procedures; and considered the need for additional training for clinicians. It was felt that additional data are required to "better understand the adverse events that were discussed during the meeting" and the panel made suggestions as to how that data might be collected going forward.

It was noted that hysteroscopic sterilisation is an important option for women who are not good candidates for surgery and are well informed regarding potential risks. The panel suggested that women with a known hypersensitivity to metal, women with autoimmune disease, women with a history of pelvic inflammatory disease and women with a history of abnormal uterine bleeding may be less suitable candidates for Essure.

In the UK, adverse incidents relating to medical devices are robustly monitored by the Medicines and Healthcare Products Regulatory Agency (MHRA). The MHRA have stated that they currently have no safety concerns relating to use of Essure devices in the UK. It is important that Essure-related adverse events continue to be reported to the MHRA.

The Faculty of Sexual and Reproductive Healthcare (FSRH) guideline, Male and Female Sterilisation (September 2014) [1] gives advice based on the available evidence and expert opinion relating to eligibility for Essure (including nickel allergy,

pelvic infection and abnormal bleeding), the insertion procedure and immediate complications, confirmatory testing, long-term complications and removal. In the absence of new trial data, there is no indication for change to these recommendations at the current time on the basis of the case reports presented to the FDA.

Hysteroscopic sterilisation with Essure increases contraceptive choice and offers an alternative to surgical sterilisation, particularly for women with contraindications to surgery. However women must be fully informed regarding known potential complications. The FSRH is confident in the MHRA's regulatory process for medical devices, and the Clinical Effectiveness Unit will continue to monitor emerging evidence. The FSRH supports the FDA recommendation that collection of further data relating to Essure adverse events is essential to inform evidence-based practice and ensure that women can make fully informed decisions regarding use of Essure.

1. FSRH Guideline: Male and Female Sterilisation, Sept 2014 http://www.fsrh.org/pdfs/MaleFemaleSterilisationSummary.pdf

2. Brief Summary of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Advisory Committee Meeting – September 24, 2015 http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/medicaldevices/medicaldevicesadvisorycommittee