End of the road for Essure®?

I am writing to draw readers' attention to a letter dated 31 May 2017 addressed to UK healthcare professionals from Bayer plc, in which that company announced that it had decided to discontinue sales of Essure®, their hysteroscopic female sterilisation device, from 1 September 2017.

Essure uses metal and polyester fibre 'microinserts' that are passed into the proximal parts of the fallopian tubes to occlude them by fibrosis. It was approved for use in the USA in 2002 and in the UK by NICE, the National Institute for Health and Clinical Excellence, in 2009.[1] The device was reviewed in this journal in 2008, with the conclusion "Further long-term data on Essure are awaited with interest"[2] – indeed, it was the requirement for such data that delayed NICE's ultimate approval.

Initial information suggested that Essure's effectiveness was equal to that of laparoscopic tubal occlusion, but with the benefit of not requiring abdominal entry or even general anaesthesia and that it could therefore be offered as an 'office' procedure. But it had the disadvantage of needing additional contraception for 3 months until confirmation of correct placement of the inserts by imaging. Initially it was advised that this should be by hysterosalpingogram, but later plain X-ray or ultrasound were deemed to be acceptable in most cases. The requirement for an additional intervention for follow-up was one reason why I did not offer the method to my patients.

However, as time went on, increasing reports of adverse events came to light. These included persistent pain, uterine or tubal perforation, device migration, heavy or irregular bleeding, and suspected allergy or hypersensitivity reactions, particularly to nickel, one of the components of the inserts. As those reports were generally not the result of well-conducted clinical trials, their significance could not be judged against the number of women for whom the procedure was completely acceptable, but some of the problems led to women requiring significant surgery such as salpingectomy or hysterectomy; a 2015 USA observational cohort study reported a more than 10-fold higher risk of undergoing reoperation within the first year compared with patients undergoing laparoscopic sterilisation.[3] Over 50% of the 8048 women who underwent Essure placement in that study had the procedure performed under general anaesthesia – hardly an 'office' procedure for them. By early May 2017 the United States Food and Drugs Administration had received over 27 000 reports of possible Essure-related problems[4] and Bayer are facing numerous cases of litigation in the USA.

Bayer's letter states that the reason for their decision was that "recently the demand for Essure in many markets has significantly declined and this trend is not expected to change", and that they believe that "with the availability of a number of alternative

sterilisation and long acting contraceptive options, you will continue to find suitable contraceptive options for your patients".

Of course, practitioners do continue to have such options. But it seems unlikely that other hysteroscopic, or indeed any 'office-based' female sterilisation procedures, will become available to replace Essure in the foreseeable future.

David H Horwell

UK/Europe Advisory Editor, *Journal of Family Planning and Reproductive Health Care*, Retired Consultant Gynaecologist, Harpenden, UK

Competing interests None declared.

Provenance and peer review Not commissioned; internally peer reviewed.

Published Online First 16 June 2017

J Fam Plann Reprod Health Care 2017;**43**:240–241. doi:10.1136/jfprhc-2017-101850

REFERENCES

1 National Institute for Health and Care Excellence. Hysteroscopic Sterilisation by Tubal Cannulation and Placement of Intrafallopian Implants. Interventional Procedures Guidance [IPG315]. 2009 https://www.nice.org.uk/guidance/ipg315 (accessed 6 June 2017).
2 Sagili H, Divers M. Hysteroscopic sterilisation with Essure: a promising new alternative to tubal ligation? *J Fam Plann Reprod Health Care* 2008;34:99–102.
3 Mao J, Pfeifer S, Schlegel P, *et al*. Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study. *BMJ* 2015;351:h5162.
4 U.S. Food and Drug Administration. FDA Activities: Essure. Updated 8 May 2017. https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm (accessed 22 June 2017).