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The Scottish Government
Riaghaltas na h-Alba

Primary Care Leads
NHS Scotland Health Board Medical Directors

30 June 2022

Dear colleague

INFORMATION FOR GPS AND SECONDARY CARE CLINICIANS ON ESSURE CONTRACEPTIVE DEVICE

Key points:

- In recent months the issue of complications experienced by patients who have been implanted with the Essure contraceptive device has been of heightened interest among members of the public and media.
- This letter is to raise awareness of the device and its potential complications among Scottish clinicians, and to stress the importance of a consistent approach and clear treatment pathway for any women experiencing complications as a result of this device

Actions:

- Distribute this letter to relevant individuals to raise awareness of the Essure implant and it's potential complications among GPs and secondary care clinicians who may be involved in the care of women affected by this device.

The Essure implant is a permanent birth control device that was used in the UK from 2009 until 2017. It was a small metal coil designed to be inserted into a woman's fallopian tubes via a non-invasive procedure, intended to create scar tissue in the tubes that permanently halts the passage of eggs down into the uterus. About 750,000 women received the device around the world and it is understood that, in Scotland, approximately 700 women were implanted with the device prior to withdrawal in 2017.

After having the device implanted, some women have reported side effects such as pain, bleeding, bloating, unwanted pregnancies, and tubal perforation. The US Food and Drug Administration (FDA), who are responsible for the safety of medical devices in the USA, has stated that on some occasions surgical extraction and hysterectomies have been required.

Recent history of the device
Essure was removed from the UK market in September 2017 following the suspension of the device CE mark when the manufacturer permanently withdrew the device from the EU market. The Medicines and Healthcare products Regulatory Agency (MHRA) confirms that suspension of the CE mark was on commercial grounds and not related to safety or quality issues.

The USA did not cease use of the device until 2019, after extensive side effects and complications were reported, and as a result there has been widespread litigation in the USA that is likely to continue to attract widespread media and public interest.

The FDA recently published interim results of a five year post-market surveillance study. The FDA's interim results indicated that:

- The rate of device removal for all Essure patients in its study, for any reason, was 10 per cent.
- Reasons for removal included patient request, management of adverse events, Essure removal in conjunction with other gynaecologic surgery, and patients not being able to rely on the device for permanent birth control.

The MHRA has advised that it plans to carry out a study of data that it has been provided with by the FDA in relation to this post-market surveillance.

Action required by clinicians
Colleagues are asked to ensure the following:

- That a clear referral pathway exists, within each Health Board, for any women experiencing complications as a result of this device, and that both clinicians and patients know what this looks like.

- That all women who suspect the device may be related to symptoms they are experiencing, such as persistent pain, are carefully listened to and have their concerns taken seriously. They should, at all times, be encouraged to talk to their clinicans about what steps may be appropriate. It is important to note, however, that the FDA advises that women who have been using Essure successfully can and should continue to do so.

- That any woman presenting to general practice with symptoms which may be related to an Essure implant, or who wishes removal, is referred to gynaecology specialists for investigation of symptoms, following local pathways.

- Where any patient requests a second opinion, clinicians take care to provide necessary support, advice, and assistance.

- Where treatment of complications is considered appropriate, sharing information with patients and allowing them to consider the treatment options available is fundamental. Device removal has its own risks, and healthcare providers should discuss the benefits and risks of any procedure with their patients before they decide on the best option for them. Patients must understand and consent to any procedure, and their decision must be recorded in the patient record.

- That any adverse incident relating to the device is reported to Health Facilities Scotland's Incident Reporting and Investigating Centre (IRIC: IRIC website).Patients should also be encouraged to report any adverse events through the MHRA Yellow Card Scheme.

Information resources
We are exploring the possibility of putting information about Essure on the NHS Inform website as a resource for both patients and clinicians. In the meantime, clinicians may find the following links helpful:

- FDA - Information for Patients and Health Care Providers: Essure | FDA
- FDA - Interim Results from Required Essure Postmarket Surveillance Study
- MHRA – 2017 statement on Essure devices

I would be grateful if you would ensure that this letter is distributed to appropriate clinicians and other relevant individuals within your Health Board area.

Yours sincerely

Professor Sir Gregor Smith
Chief Medical Officer