New FSRH guideline on the progestogen-only implant

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The UK Faculty of Sexual & Reproductive Healthcare (FSRH) has updated its 2014 guideline[1] on the progestogen-only implant, reexamining old evidence, reflecting new evidence and highlighting changes in practice. While much remains unchanged, important new information and guidance is provided about the change in recommended etonogestrel implant (ENG-IMP) insertion site, duration of ENG-IMP use and expected bleeding patterns, and the evidence around the highly topical risk of intravascular insertion is set out.

The ENG-IMP is still the only available contraceptive implant in the UK. Evidence suggests that it provides highly effective contraception for 3 years even in users with raised body mass index. Most of the reported pregnancies during ENG-IMP use were conceived before implant insertion or established efficacy, or where efficacy was reduced by enzyme-inducing medication. There have been very few reported pregnancies during established use with no accountable reason for contraceptive failure.

Clarity is provided around the routine use of the ENG-IMP in the fourth year (note this varies from COVID-19 guidance.) There is not enough evidence to advise that the ENG-IMP should be routinely used for 4 years. However, based on observational studies, the risk of pregnancy in the fourth year of use appears to be very low and possibly comparable with the contraceptive effectiveness of oral contraception. Reflecting this, the guidance has also changed on switching from the ENG-IMP in its fourth year of use to intrauterine contraception. Up to 4 years after ENG-IMP insertion, if a pregnancy test is negative on the day, all intrauterine methods can be inserted even if there has been unprotected intercourse in the last 21 days. Condoms are needed for 7 days after insertion of a levonorgestrel intrauterine system in this situation, and a follow-up pregnancy test is required.

Clinical data do not exist to inform which ENG-IMP insertion site is associated with the lowest risk of complications. The revised insertion site recommended in the guideline reflects the findings of a manufacturer-funded anatomical study and aligns with their recommendation on ENG-IMP site insertion (Merck Sharp & Dohme Limited (MSD)).[2] In the study, cadaveric arms were dissected and the site on the inner upper arm with the fewest neurovascular structures was identified. Theoretically, this site should minimise risk of ENG-IMP insertion- or removal-related neurovascular damage, or intravenous insertion.

The insertion and removal procedure techniques outlined in the new guideline are based on the opinion and experience of the guideline development group (GDG) and are a guide to good practice where evidence is lacking. Emphasis is placed on subdermal insertion, avoiding the sulcus between biceps and triceps. It is made clear that there is no need to routinely change the arm in which the ENG-IMP is inserted after any number of previous ENG-IMP insertions.

The medical eligibility criteria for ENG-IMP use have not changed in the updated guideline, which reminds us that the only absolute contraindication is current breast cancer. UK Medical Eligibility Criteria Category 3 (UKMEC3) includes previous breast cancer, decompensated liver disease, and cardiovascular disease that developed during ENG-IMP use (although evidence suggests that cardiovascular events are not increased with ENG-IMP use and pregnancy poses a greater cardiovascular risk, which highlights the importance of weighing up risks versus benefits).

With regard to bone mineral density, there has been no new published evidence since the previous guideline. The GDG have, however, reanalysed the available evidence and have been cautious in its interpretation, stating that although the effect of ENG-IMP use on bone mineral

density is unlikely to be clinically significant, there is not enough evidence to say that there is no effect.

To ensure that users have realistic expectations about bleeding patterns associated with ENG-IMP use and are able to make informed choices, key information points and clinical recommendations are given that support counselling about unpredictable bleeding patterns. The new guideline summarises the existing evidence concisely, reminding us that most users will have fewer days of bleeding or periods than with combined hormonal contraceptive use, but that the pattern is less predictable. Bleeding is often irregular, may range from no bleeding to bleeding every day, the pattern of individual users is unpredictable, and bleeding often changes over time. Unfortunately, there are no new evidence-based ways of managing bleeding and, as in previous guidance, if eligible, users may try combined hormonal contraception or, if not, mefenamic acid. There is no new evidence to say if the progestogen-only pill is a safe, effective strategy.

The guideline helpfully provides key information points and clinical recommendations about the potential non-contraceptive benefits associated with ENG-IMP use, namely its use by women experiencing dysmenorrhoea, heavy menstrual bleeding, and endometriosis, and to provide endometrial protection in polycystic ovarian syndrome. This will be a useful addition to guide discussions about contraceptive options for women with coexisting gynaecological conditions.

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