

Contraception for Women Aged Over 40 Years: CEU Response to Public Consultation

The CEU would like to thank the individuals and representatives from our stakeholder organisations who have provided feedback.

Comments on recommendations and main body of text

Individual /organisation	Location in guideline	Comments	CEU's Response
Family Planning Association	Table 8 and the paragraph below	Table 8 mentions Mirena can remain in situ until age 55 – does this include Jaydess and Levosert or just Mirena?	No, this just relates to Mirena at the present time.
Individual/FSRH Member	Page 12: endometrial ablation	This section only discusses the IUS but the use of the IUD should be considered too.	Thank for taking time to comment. It would be a highly unusual situation where a woman was having an IUD following endometrial ablation so this was not considered.
	Page 12: 5.4.4	"Women using a Mirena for contraception who were under 45 at the time of Mirena insertion may have an immediate replacement of their device between 5 and 7 years if a pregnancy test is negative. If they have had intercourse in the preceding three weeks then, for completeness, another pregnancy test is advised for no sooner than 3 weeks after the last episode of intercourse." Good to have a reminder about avoiding sex for 5? Or 7? Days prior to removal in case reinsertion not possible.	We believe that is too much detail for this document.
	Page 13: 5.4.4	"As the risk of pregnancy is extremely low once a woman reaches age 55, contraception can be stopped at that age." Suggest add "even if still getting some PV bleeding or spotting."	We will amend to concur with the wording on page 26 as below.
	Page 16: recommendations	"Combined oral contraception (COC) with levonorgestrel or norethisterone should be considered first line for women over 40 due to the potentially lower VTE risk ... ?" add to recommendation – "especially when initiating COCP"	We think this is implicit already in the statement.

	Page 16: recommendations	"COC with ≤ 30 μg ethinylestradiol should be considered first line for women over 40 due to the potentially lower risks of VTE, cardiovascular disease and stroke compared to formulations containing higher doses of estrogen." "Do the readers need some guidance around whether they should consider switching women to a 20mcg pill once over 40 – if already established on a 30mcg pill.	We think this would come down to clinical judgement for each individual.
	Page 23: Barrier methods	"Oil-based lubricants can damage latex condoms and non-oil-based lubricants or plastic condoms should be used with these." Please expand to discuss more about lubricants and vaginal moisturizers which women >40 are more likely to be using due to vaginal dryness and possible effect on condoms and diaphragms.	We will change initial wording to be "Oil based lubricants and moisturisers can damage latex condoms...and non-oil-based products or plastic condoms" Otherwise more detail is outwith the scope of the guidance - too many variables.
	Page 26	"Women using CHC have very suppressed levels of estradiol, FSH and LH so these cannot be used to inform advice regarding menopausal status." Add " even if measured during hormone free interval."	We will add this in.
	Page 26	"In general, all women can cease contraception at the age of 55 as spontaneous conception after this age is exceptionally rare even in women still having occasional menstrual bleeding." What about women still having regular menstrual bleeding?	We will amend to read "still having any menstrual bleeding."
Pharmaceutical company	Page 13	We would like to make you aware of the 4 year data of the ongoing ACCESS IUS study (A Comprehensive Contraceptive Efficacy and Safety Study of an IUS), which was used for the contraceptive indication for Levosert; this data was recently presented as an eposter at the 65th Annual Clinical and Scientific Meeting of the American College of Obstetrician and Gynecologists in May 2017. It received a Blue Ribbon poster designation at this meeting. The abstract has been published. Reference: Thomas M, et al. Four-Year Efficacy and Safety of the Liletta Levonorgestrel Intrauterine System. (Liletta is the brand name of the product Levosert in the US)	Thank you for these comments. We note that the SPC still states removal after 3 years (checked 4th August 2017). We will insert a sentence to say that "New data are likely to emerge that may support longer duration of usage" in page 13.

	<p>ACOG Conference programme available here [Accessed July 2017]: http://annualmeeting.acog.org/wp-content/uploads/2017/05/2017ACSM_FinalProgram-bd.pdf</p> <p>The abstract is available here [Accessed July 2017]: http://journals.lww.com/greenjournal/Abstract/2017/05001/Four_Year_Efficacy_and_Safety_of_the_Liletta_R_.35.aspx</p> <p>x</p> <p>The ACCESS IUS was designed to assess efficacy and safety of LNG-releasing IUS for up to 7 years of contraception in a diverse range of women who request long-term, reversible contraception. In December 2016, Medicines360 announced that the study duration is prolonged up to 8 years to provide clinical data to support longest duration period of the hormonal product.</p> <p>Reference: Medicines360. A study of a levonorgestrel-releasing intrauterine system for long-term, reversible contraception.</p> <p>Available [Accessed July 2017]: https://clinicaltrials.gov/ct2/show/NCT00995150?term=medicines360&rank=1</p> <p>To fully understand the potential for Liletta to have a longer duration of action, Creinin MD, et al. conducted a study to determine LNG content and estimate LNG release rates over approximately 5½ years of product use.</p> <p>According to Creinin MD, et al., the Liletta LNG content and release rates are comparable to published data for another LNG 52-mg IUS. The calculated LNG content and release rate curves support the continued evaluation of Liletta as a contraceptive for 5 or more years of use.</p> <p>Reference: Creinin MD, et al. Levonorgestrel release rates over 5 years with the Liletta® 52-mg intrauterinesystem. <i>Contraception</i>. 2016; 94(4):353-356.</p> <p>In conclusion, Levosert is currently licensed for women</p>	
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		and doctors with 3 years of product use but the period of use is going to be extended yearly up to 8 years. The 4-year duration period variation dossier was submitted to the Authorities in June 2017.	
	References	Ref No 85: As Gedeon Richter Plc is now the Marketing Authorisation Holder (MAH), we suggest this reference is updated to reflect the same. The emc website has been updated on 10th July 2017. http://www.medicines.org.uk/emc/medicine/30120	Noted and changed.
Women's Health Forum, Royal College of Nursing	General comments	Very good. We have no other comments and think that this has covered the subject very well and will be useful in practice.	Thank you for your comments.

All comments on *Contraception for Women Aged Over 40 Years* can be sent directly to the CEU via the FSRH website (www.fsrh.org).

The Clinical Effectiveness Unit (CEU) was formed to support the Clinical Effectiveness Committee of the Faculty of Sexual and Reproductive Healthcare (FSRH), the largest UK professional membership organisation working at the heart of sexual and reproductive healthcare. The CEU promotes evidence based clinical practice and it is fully funded by the FSRH through membership fees. It is based in Edinburgh and it provides a member's enquiry service, evidence based guidance, new SRH product reviews and clinical audit/research. Find out more here.