

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Centre for Clinical Practice – Surveillance Programme

### *Surveillance review consultation document*

#### **8-year surveillance review of CG30: Long-acting reversible contraception - the effective and appropriate use of long-acting reversible contraception**

##### ***Background information***

Guideline issue date: October 2005

2-year review: 2007/2008 (no update)

5-year review: 2010/2011 (no update)

8-year review: 2013

##### ***Surveillance review recommendation***

Through the 8-year surveillance review of CG 30 no new evidence which may potentially change the direction of current guideline recommendations was identified. The proposal is not to update the guideline at this time.

##### ***Main conclusions of previous (2-year & 5-year) surveillance reviews***

CG30 was previously reviewed for update in 2007 and 2010. At both review points, no new evidence was identified which would change the direction of guideline recommendations. The review recommendations at both review points were that the guideline should not be considered for an update.

However, subsequent to the 5-year review, it came to the attention of NICE that Implanon®, the progestogen-only subdermal implant recommended in the guideline, has been discontinued and replaced by Nexplanon®. Nexplanon® contains the same amount of the same drug as Implanon®, but the summaries of product characteristics for the two devices are not identical.

In the light of the change in the implant available, the section of the guideline that makes recommendations on progestogen-only subdermal implants was considered as one of the pilots for the rapid update programme and was signed-off by Guidance Executive as a rapid update topic in June 2013.

### **Main findings of current (8-year) surveillance review**

A literature search for randomised controlled trials and systematic reviews was carried out for articles published between October 2010 (the end of the search period for 5-year review in 2010) and August 2013 and relevant abstracts were assessed. Clinical feedback was also obtained from members of the guideline development group (GDG) through a questionnaire survey. New evidence was identified relating to all four clinical areas of the guideline that were considered for the 8-year review (the section of the guideline on progestogen-only subdermal implants was not reviewed as it has been scheduled to undergo a rapid update)

<b>Evidence summary of clinical area</b>	<b>GDG/clinical perspective</b>	<b>Impact</b>
<b>Contraceptive use and principles of care</b>		
Fourteen studies <sup>1-14</sup> were identified; findings of studies were consistent with guideline recommendations.	No clinical feedback was provided for this section of the guideline.	New evidence is consistent with guideline recommendations.
<b>Copper intrauterine devices (IUDs)</b>		
Forty four studies <sup>15-58</sup> were identified; findings of studies were consistent with guideline recommendations.	No clinical feedback was provided for this section of the guideline.	New evidence is consistent with guideline recommendations.
<b>Intrauterine system (IUS)</b>		
Fourteen studies <sup>59-72</sup> were identified consistent with guideline recommendations.  Two of these studies <sup>64,70</sup> relate to a new low-dose levonorgestrel intrauterine system that is due to launch in the UK and to be marketed as Jaydess <sup>®</sup> (Bayer). The Medicines and Prescribing Centre (MPC) at NICE is due to produce a report on this new low-dose levonorgestrel intrauterine system through the Evidence Summaries: New Medicines (ESNM) programme (expected publication date July 2014).	No clinical feedback was provided for this section of the guideline.	New evidence is consistent with guideline recommendations. However, the guideline should be read in conjunction with the soon to be published MPC report on this new low-dose levonorgestrel intrauterine system.
<b>Progestogen-only injectable contraceptives (POICs)</b>		
Sixteen studies <sup>73-88</sup> were identified that would not change the direction of current guideline recommendations.  However, a <a href="#">report</a> has been produced by the Evidence Summaries: New Medicines (ESNM) programme of the Medicines and Prescribing Centre (MPC) at NICE on a newly licenced subcutaneous formulation of medroxyprogesterone, called Sayana Press <sup>®</sup> .	Feedback from the GDG related to the need for guidance on Sayana Press <sup>®</sup> the new subcutaneous formulation of depot medroxyprogesterone acetate that was launched in the UK in 2013.	New evidence is consistent with guideline recommendations. However, the guideline should be read in conjunction with <a href="#">ESNM31 Long-acting reversible contraception: subcutaneous depot medroxyprogesterone acetate (DMPA-SC)</a> , the MPC report on Sayana Press <sup>®</sup> .

### ***Anti-discrimination and equalities considerations***

None identified.

### ***Conclusion***

Two new formulations of existing drugs have been identified and are the subject of evidence summaries prepared by the Medicines and Prescribing Centre at NICE under their Evidence Summaries: New Medicines (ESNM) programme:

- ESNM31 Long-acting reversible contraception: subcutaneous depot medroxyprogesterone acetate (DMPA-SC)
- ESNMxx Long-acting reversible contraception: low-dose levonorgestrel intrauterine-releasing system (in development, expected to be published in July 2014)

In light of the publication of these summaries it is felt that the guidance should not be updated at this time but evidence on the above will be considered further at the next review point in 2015.

The guideline should not be considered for an update at this time. However, the guideline should be read in conjunction with evidence summaries on the two new formulations.

## References

1. Arrowsmith ME, Aicken CR, Saxena S et al. (2012) Strategies for improving the acceptability and acceptance of the copper intrauterine device. *Cochrane database of systematic reviews* (Online) 3:2012.
2. Blanchard K, Holt K, Bostrom A et al. (2011) Impact of learning HIV status on contraceptive use in the MIRA trial. *Journal of Family Planning and Reproductive Health Care* 37:October.
3. Blumenthal PD, Voedisch A, and Gemzell-Danielsson K. (2011) Strategies to prevent unintended pregnancy: increasing use of long-acting reversible contraception. *Human Reproduction Update* 17:121-137.
4. Carneiro Gomes Ferreira AL, Impieri SA, Evangelista PR et al. (2011) The effectiveness of contraceptive counseling for women in the postabortion period: An intervention study. *Contraception* 84:October.
5. Chaovitsaree S, Noi-um S, and Kietpeerakool C. (2012) Review of postpartum contraceptive practices at Chiang Mai University hospital: Implications for improving quality of service. *Medical Principles and Practice* 21:February.
6. Church E, Sengupta S, and Chia KV. (2010) The contraceptive implant for long acting reversible contraception in patients undergoing first trimester medical termination of pregnancy. *Sexual & reproductive healthcare : official journal of the Swedish Association of Midwives* 1:105-109.
7. Dehlendorf C, Ruskin R, Grumbach K et al. (2010) Recommendations for intrauterine contraception: A randomized trial of the effects of patients' race/ethnicity and socioeconomic status. *American Journal of Obstetrics and Gynecology* 203:October.
8. Dehlendorf C, Grumbach K, Vittinghoff E et al. (2011) A study of physician recommendations for reversible contraceptive methods using standardized patients. *Perspectives on Sexual & Reproductive Health* 43:224-229.
9. Garbers S, Meserve A, Kottke M et al. (2012) Randomized controlled trial of a computer-based module to improve contraceptive method choice. *Contraception* 86:October.
10. Garbers S, Meserve A, Kottke M et al. (2012) Tailored health messaging improves contraceptive continuation and adherence: Results from a randomized controlled trial. *Contraception* 86:November.
11. Halpern V, Lopez LM, Grimes DA et al. (2011) Strategies to improve adherence and acceptability of hormonal methods of contraception. [Update of *Cochrane Database Syst Rev.* 2006;(1):CD004317; PMID: 16437483]. *Cochrane Database of Systematic Reviews* CD004317.
12. Peipert JF, Zhao Q, Allsworth JE et al. (2011) Continuation and satisfaction of reversible contraception. *Obstetrics & Gynecology* 117:1105-1113.

13. Simmons KB, Edelman AB, Li H et al. (2013) Personalized contraceptive assistance and uptake of long-acting, reversible contraceptives by postpartum women: A randomized, controlled trial. *Contraception* 88:July.
14. Tang JH, Dominik R, Re S et al. (2013) Characteristics associated with interest in long-acting reversible contraception in a postpartum population. *Contraception* 88:July.
15. Alton TM, Brock GN, Yang D et al. (2012) Retrospective Review of Intrauterine Device in Adolescent and Young Women. *Journal of Pediatric and Adolescent Gynecology* 25:June.
16. Bednarek PH, Creinin MD, Reeves MF et al. (2011) Immediate versus delayed IUD insertion after uterine aspiration. *New England Journal of Medicine* 364:09.
17. Bednarek PH, Micks EA, Edelman AB et al. (2013) The effect of nitroprusside on IUD insertion experience in nulliparous women: A pilot study. *Contraception* 87:April.
18. Betstadt SJ, Turok DK, Kapp N et al. (2011) Intrauterine device insertion after medical abortion. *Contraception* 83:June.
19. Bhutta SZ, Butt IJ, and Bano K. (2011) Insertion of intrauterine contraceptive device at caesarean section.[Erratum appears in *J Coll Physicians Surg Pak*. 2011 Nov;21(11):717]. *Jcsp, Journal of the College of Physicians & Surgeons - Pakistan* 21:527-530.
20. Black K, Lotke P, Buhling KJ et al. (2012) A review of barriers and myths preventing the more widespread use of intrauterine contraception in nulliparous women. *European Journal of Contraception and Reproductive Health Care* 17:October.
21. Brahmi D, Steenland MW, Renner R-M et al. (2012) Pregnancy outcomes with an IUD in situ: A systematic review. *Contraception* 85:February.
22. Cameron ST, Glasier A, Cooper A et al. (2013) Does a full bladder assist insertion of intrauterine contraception? A randomised trial. *Journal of Family Planning and Reproductive Health Care* 39:July.
23. Castellsague X, Diaz M, Vaccarella S et al. (2011) Intrauterine device use, cervical infection with human papillomavirus, and risk of cervical cancer: A pooled analysis of 26 epidemiological studies. *The Lancet Oncology* 12:October.
24. Cremer M, Bullard KA, Mosley RM et al. (2011) Immediate vs. delayed post-abortal copper T 380A IUD insertion in cases over 12 weeks of gestation. *Contraception* 83:June.
25. Curtis KM, Nanda K, and Kapp N. (2009) Safety of hormonal and intrauterine methods of contraception for women with HIV/AIDS: a systematic review. *AIDS* 23:Suppl-67.
26. Dijkhuizen K, Dekkers OM, Holleboom CAG et al. (2011) Vaginal misoprostol prior to insertion of an intrauterine device: An RCT. *Human Reproduction* 26:February.

27. Dinger J, Bardenheuer K, and Minh TD. (2011) Levonorgestrel-releasing and copper intrauterine devices and the risk of breast cancer. *Contraception* 83:March.
28. Elseddek MS. (2012) Puerperal and menstrual bleeding patterns with different types of contraceptive device fitted during elective cesarean delivery. *International Journal of Gynaecology & Obstetrics* 116:31-34.
29. Fouda UM, Yossef D, and Gaafar HM. (2010) Uterine artery blood flow in patients with copper intrauterine device-induced abnormal uterine bleeding. *Middle East Fertility Society Journal* 15:July.
30. Gemzell-Danielsson K, Mansour D, Fiala C et al. (2013) Management of pain associated with the insertion of intrauterine contraceptives. *Human Reproduction Update* 19:July.
31. Godfrey EM, Folger SG, Jeng G et al. (2013) Treatment of bleeding irregularities in women with copper-containing IUDs: A systematic review. *Contraception* 87:May.
32. Goldstuck N. (2012) Assessment of uterine cavity size and shape: a systematic review addressing relevance to intrauterine procedures and events. *African Journal of Reproductive Health* 16:Sep.
33. Grimes DA, Lopez LM, Schulz KF et al. (2010) Immediate postabortal insertion of intrauterine devices. SO: Cochrane Database of Systematic Reviews .
34. Grimes DA, Lopez LM, Schulz KF et al. (2010) Immediate post-partum insertion of intrauterine devices. SO: Cochrane Database of Systematic Reviews .
35. Guirguis-Blake J. (2011) Copper intrauterine device vs. depot medroxyprogesterone acetate for contraception. *American Family Physician* 83:January.
36. Hofmeyr GJ, Singata M, and Lawrie TA. (2010) Copper containing intra-uterine devices versus depot progestogens for contraception. SO: Cochrane Database of Systematic Reviews .
37. Hou S-P, Chen O-J, Huang L-H et al. (2013) Medical methods for cervical ripening before the removal of intrauterine devices in postmenopausal women: A systematic review. *European Journal of Obstetrics Gynecology and Reproductive Biology* 169:July.
38. Hu X, Li L, Zou Y et al. (2013) A multicenter comparative study of UCu200, TCu380A, and medicated -IUD devices inserted immediately after vacuum aspiration. *International Journal of Gynecology and Obstetrics* 122:July.
39. Ibrahim ZM and Ahmed WAS. (2013) Sublingual misoprostol prior to insertion of a T380A intrauterine device in women with no previous vaginal delivery. *European Journal of Contraception and Reproductive Health Care* 18:August.

40. Karabayirli S, Ayrm AA, and Muslu B. (2012) Comparison of the Analgesic Effects of Oral Tramadol and Naproxen Sodium on Pain Relief During IUD Insertion. *Journal of Minimally Invasive Gynecology* 19:September.
41. Khan SA, UI AZ, Fouzia et al. (2010) A comparative trial of copper T 380 and Cu 375 IUCD. *Journal of Ayub Medical College, Abbottabad* : JAMC 22:2010-2Sep.
42. Lowe RF and Prata N. (2013) Hemoglobin and serum ferritin levels in women using copper-releasing or levonorgestrel-releasing intrauterine devices: A systematic review. *Contraception* 87:April.
43. Maguire K, Davis A, Rosario TL et al. (2012) Intracervical lidocaine gel for intrauterine device insertion: A randomized controlled trial. *Contraception* 86:September.
44. McNicholas CP, Madden T, Zhao Q et al. (2012) Cervical lidocaine for IUD insertional pain: A randomized controlled trial. *American Journal of Obstetrics and Gynecology* 207:November.
45. Mirmohamad AM, Khazaie F, Rahnama P et al. (2013) Effect of lavender on pain during insertion of intrauterine device: A clinical trial. *Journal of Babol University of Medical Sciences* 15:2013.
46. Mody SK, Kiley J, Rademaker A et al. (2012) Pain control for intrauterine device insertion: A randomized trial of 1% lidocaine paracervical block. *Contraception* 86:December.
47. Mohammad-Alizadeh-Charandabi S, Seidi S, and Kazemi F. (2010) Effect of lidocaine gel on pain from copper IUD insertion: A randomized double-blind controlled trial. *Indian Journal of Medical Sciences* 64:01.
48. Nelson AL and Fong JK. (2013) Intrauterine infusion of lidocaine does not reduce pain scores during IUD insertion. *Contraception* 88:July.
49. Saav I, Stephansson O, and Gemzell-Danielsson K. (2012) Early versus Delayed Insertion of Intrauterine Contraception after Medical Abortion - A Randomized Controlled Trial. *PLoS ONE* 7:e48948.
50. Scavuzzi A, Souza ASR, Costa AAR et al. (2013) Misoprostol prior to inserting an intrauterine device in nulligravidas: A randomized clinical trial. *Human Reproduction* 28:August.
51. Shimoni N, Davis A, Ramos ME et al. (2011) Timing of copper intrauterine device insertion after medical abortion: A randomized controlled trial. *Obstetrics and Gynecology* 118:September.
52. Steenland MW, Tepper NK, Curtis KM et al. (2011) Intrauterine contraceptive insertion postabortion: A systematic review. *Contraception* 84:November.

53. Swenson C, Turok DK, Ward K et al. (2012) Self-administered misoprostol or placebo before intrauterine device insertion in nulliparous women: A randomized controlled trial. *Obstetrics and Gynecology* 120:August.
54. Tepper NK, Steenland MW, Marchbanks PA et al. (2013) Hemoglobin measurement prior to initiating copper intrauterine devices: A systematic review. *Contraception* 87:May.
55. Waddington A and Reid R. (2012) More Harm Than Good: The Lack of Evidence for Administering Misoprostol Prior to IUD Insertion. *Journal of Obstetrics & Gynaecology Canada: JOGC* 34:1177-1179.
56. Wen J, Li Y, Li Y et al. (2010) Comparative cost-effectiveness of three intrauterine devices: a multi-center randomized trial. *Journal of Evidence-based Medicine* 3:76-82.
57. Whiteman MK, Tyler CP, Folger SG et al. (2013) When can a woman have an intrauterine device inserted? A systematic review. *Contraception* 87:May.
58. Wildemeersch D, Pett A, Jandi S et al. (2013) Precision intrauterine contraception may significantly increase continuation of use: A review of long-term clinical experience with frameless copper-releasing intrauterine contraception devices. *International Journal of Women's Health* 5:29.
59. Chen BA, Reeves MF, Hayes JL et al. (2010) Postplacental or delayed insertion of the levonorgestrel intrauterine device after vaginal delivery: A randomized controlled trial. *Obstetrics and Gynecology* 116:November.
60. Chen BA, Reeves MF, Creinin MD et al. (2011) Postplacental or delayed levonorgestrel intrauterine device insertion and breast-feeding duration. *Contraception* 84:499-504.
61. Chor J, Bregand-White J, Golobof A et al. (2012) Ibuprofen prophylaxis for levonorgestrel-releasing intrauterine system insertion: A randomized controlled trial. *Contraception* 85:June.
62. Dahlke JD, Terpstra ER, Ramseyer AM et al. (2011) Postpartum insertion of levonorgestrel-intrauterine system at three time periods: A prospective randomized pilot study. *Contraception* 84:September.
63. Edelman AB, Schaefer E, Olson A et al. (2011) Effects of prophylactic misoprostol administration prior to intrauterine device insertion in nulliparous women. *Contraception* 84:September.
64. Gemzell-Danielsson K, Schellschmidt I, and Apter D. (2012) A randomized, phase II study describing the efficacy, bleeding profile, and safety of two low-dose levonorgestrel-releasing intrauterine contraceptive systems and Mirena. *Fertility & Sterility* 97:616-622.
65. Godfrey EM, Memmel LM, Neustadt A et al. (2010) Intrauterine contraception for adolescents aged 14-18 years: a multicenter randomized pilot study of levonorgestrel-releasing intrauterine system compared to the Copper T 380A. *SO: Contraception* 81:123-127.

66. Heikinheimo O, Inki P, Kunz M et al. (2010) Double-blind, randomized, placebo-controlled study on the effect of misoprostol on ease of consecutive insertion of the levonorgestrel-releasing intrauterine system. *SO: Contraception* 81:481-486.
67. Hohmann HL, Reeves MF, Chen BA et al. (2012) Immediate versus delayed insertion of the levonorgestrel-releasing intrauterine device following dilation and evacuation: A randomized controlled trial. *Contraception* 85:March.
68. Lal S, Kriplani A, Kulshrestha V et al. (2010) Efficacy of mifepristone in reducing intermenstrual vaginal bleeding in users of the levonorgestrel intrauterine system. *SO: International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics* 109:128-130.
69. Madden T, Proehl S, Allsworth JE et al. (2012) Naproxen or estradiol for bleeding and spotting with the levonorgestrel intrauterine system: A randomized controlled trial. *American Journal of Obstetrics and Gynecology* 206:February.
70. Nelson A, Apter D, Hauck B et al. (2013) Two Low-Dose Levonorgestrel Intrauterine Contraceptive Systems: A Randomized Controlled Trial. *Obstetrics & Gynecology* 122.
71. Rana M, Saxena P, and Firdous N. (2012) Comparison of levonorgestrel and copper releasing intrauterine contraceptive device on body iron stores and menstrual bleeding patterns: Experience on Indian women. *European review for medical and pharmacological sciences* 16:February.
72. Sordal T, Inki P, Draeby J et al. (2013) Management of initial bleeding or spotting after levonorgestrel-releasing intrauterine system placement: A Randomized Controlled Trial. *Obstetrics and Gynecology* 121:May.
73. Abdel-Aleem H, Shaaban OM, Abdel-Aleem MA et al. (2012) Doxycycline in the treatment of bleeding with DMPA: A double-blinded randomized controlled trial. *Contraception* 86:September.
74. Abdel AH, d'Arcangues C, Vogelsong KM et al. (2013) Treatment of vaginal bleeding irregularities induced by progestin only contraceptives. *SO: Cochrane Database of Systematic Reviews* .
75. Chakhtoura Z, Canonico M, Gompel A et al. (2011) Progestogen-only contraceptives and the risk of acute myocardial infarction: A meta-analysis. *Journal of Clinical Endocrinology and Metabolism* 96:April.
76. Delvaux T and Buve A. (2013) Hormonal contraception and HIV acquisition - what is the evidence? What are the policy and operational implications? *Eur J Contracept.Reprod.Health Care* 18:15-26.
77. Dempsey A, Roca C, and Westhoff C. (2010) Vaginal estrogen supplementation during Depo-Provera initiation: a randomized controlled trial. *Contraception* 82:250-255.

78. Gerlach LS, Saldana SN, Wang Y et al. (2011) Retrospective review of the relationship between weight change and demographic factors following initial depot medroxyprogesterone acetate injection in adolescents. *Clinical Therapeutics* 33:182-187.
79. Heffron R, Donnell D, Rees H et al. (2012) Use of hormonal contraceptives and risk of HIV-1 transmission: a prospective cohort study. *SO: The Lancet infectious diseases* 12:19-26.
80. Heffron R, Mugo N, Ngure K et al. (14-1-2013) Hormonal contraceptive use and risk of HIV-1 disease progression. *AIDS* 27:261-267.
81. Li CI, Beaber EF, Tang MTC et al. (2012) Effect of depo-medroxyprogesterone acetate on breast cancer risk among women 20 to 44 years of age. *Cancer Research* 72:15.
82. Meier C, Brauchli YB, Jick SS et al. (2010) Use of depot medroxyprogesterone acetate and fracture risk. *J Clin Endocrinol.Metab* 95:4909-4916.
83. Picardo C and Ferreri S. (2010) Pharmacist-administered subcutaneous depot medroxyprogesterone acetate: a pilot randomized controlled trial. *Contraception* 82:160-167.
84. Polis CB, Phillips SJ, and Curtis KM. (2013) Hormonal contraceptive use and female-to-male HIV transmission: A systematic review of the epidemiologic evidence. *AIDS* 27:20.
85. Segall-Gutierrez P, Du J, Niu C et al. (2012) Effect of subcutaneous depo-medroxyprogesterone acetate (DMPA-SC) on serum androgen markers in normal-weight, obese, and extremely obese women. *Contraception* 86:739-745.
86. Segall-Gutierrez P, Xiang AH, Watanabe RM et al. (2012) Deterioration in cardiometabolic risk markers in obese women during depot medroxyprogesterone acetate use. *Contraception* 85:36-41.
87. van H, V, Helmerhorst FM, and Rosendaal FR. (2010) The risk of deep venous thrombosis associated with injectable depot-medroxyprogesterone acetate contraceptives or a levonorgestrel intrauterine device. *Arteriosclerosis, Thrombosis, and Vascular Biology* 30:November.
88. Walsh JS, Eastell R, and Peel NF. (2010) Depot medroxyprogesterone acetate use after peak bone mass is associated with increased bone turnover but no decrease in bone mineral density. *SO: Fertility and sterility* 93:697-701.