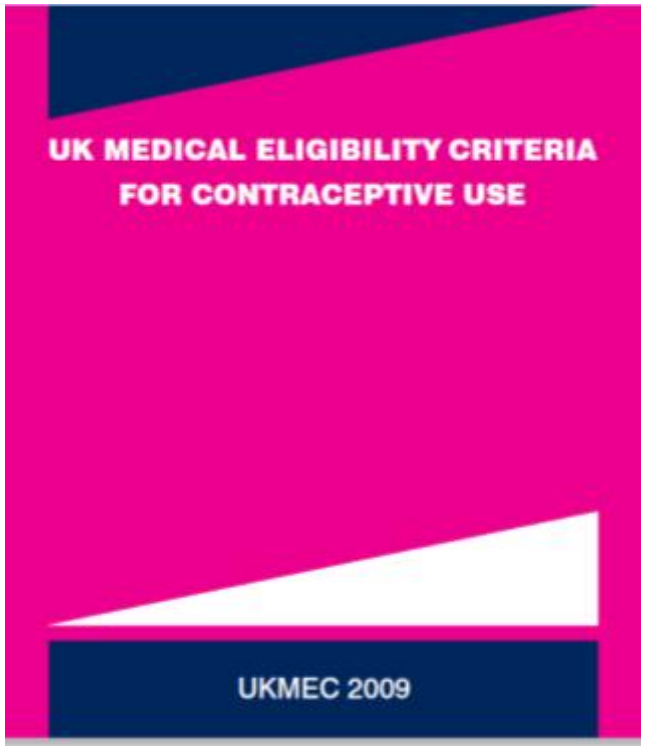
Contraception and LARC update

Sal Roberts

NEW UKMEC COMING SOON!!!!

Due End April 2016!!!



FACULTY
OF SEXUAL
& REPRODUCTIVE
HEALTHCARE
ROYAL COLLEGE OF OBSTETRICIANS & GYNAECOLOGISTS

Contraception UKMEC

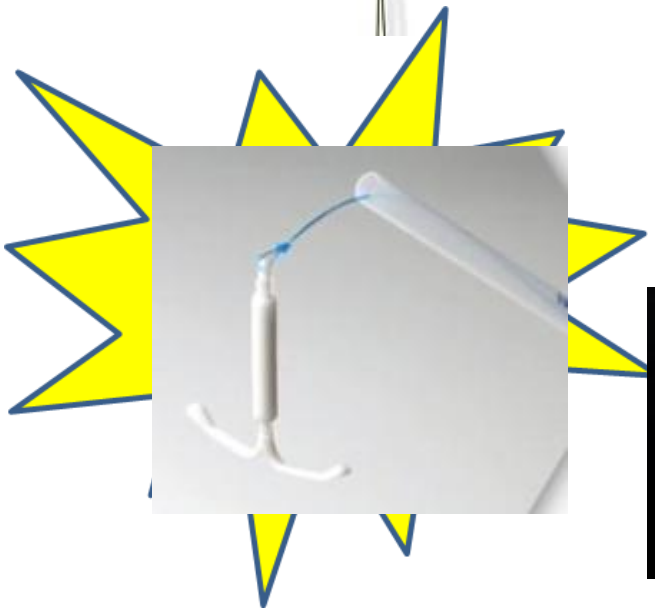
UK Category	Hormonal contraception, intrauterine devices, emergency contraception and barrier methods
1.	A condition for which there is no restriction for the use of the contraceptive method
2.	A condition where the advantages of using the method generally outweigh the theoretical or proven risks
3.	A condition where the theoretical or proven risks generally outweigh the advantages of using the method. The provision of a method requires expert clinical judgement and/or referral to a specialist contraceptive provider, since use of the method is not usually recommended unless other more appropriate methods are not available or not acceptable
4.	A condition which represents an unacceptable risk if the contraceptive method is used

The Contraceptive Consultation

Offer ***all*** methods unless contraindicated

- Age alone is no contra-indication - UKMEC
- LARC methods should be encouraged (NICE)
- Understanding what the women means when asking for the “pill”
- Medical risk assessment / Contraception history
- Full sexual history – warts and all!!
- Tailor consultation to women's understanding and beliefs
- Information and choice are fundamental to continuation

LARC Methods



Contraceptive Efficacy (in the US)

Method	%Women experiencing an unintended pregnancy within 1st year of use		% Women continuing with use at 1 year
	Typical Use	Perfect use	
No Method	85	85	-
Spermicides	28	18	42
Fertility awareness	24	0.4-5	47
Withdrawal	22	4	46
Condom Female	21	5	41
Condom Male	18	2	43
COC +POP	9	0.3	67
Patch	9	0.3	67
Nuvaring	9	0.3	67
Depo Provera	6	0.2	56
IUD	0.8	0.6	78
IUS	0.2	0.2	80
Implant	0.05	0.05	84
Female Sterilization	0.5	0.5	100
Male Sterilization	0.15	0.1	100

Trussell J 2011 Contraceptive failure in the US *Contraception* 83: 397-404

Costs

LARC	Full cost	Average Duration Years	Average Annual Cost
IUD	£208	3.36	£62
IUS	£286	3.32	£86
Implant	£281	2.24	£125
Injectable	£403	2.56	£158

Updated figures - Adapted from NICE. Clinical guideline no.30. Long Acting Reversible Contraception. Oct 2005. MIMS 2012

Implant

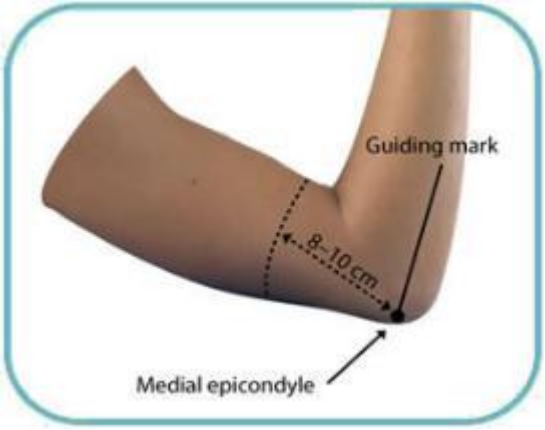
- Nexplanon®
- 3years licence
- 68mg Etonogestrel
- Release rate: 60-70 µg/day by week 5-6

  35-45 µg/day at 1st yr

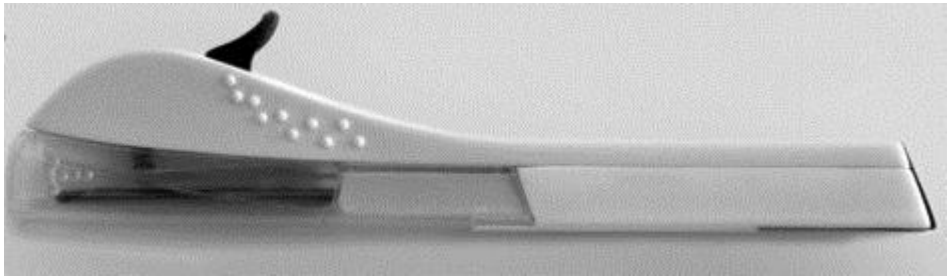
  30-40 µg/day at 2nd yr

  25-30 µg/day at the end 3rd yr
- Barium core = radiopaque

Implant



- Inserted sub-dermally, inner aspect of arm
- 8–10 cm above the medial epicondyle of the humerus



- Changed insertion device
- Legal aspects of contraceptive Implants – Sam Rowlands 2010 “insertion over the biceps/triceps groove is unwise” now 8-10cm above the medial epicondyle of the humerus which is behind the groove!

http://wrap.warwick.ac.uk/4916/1/WRAP_Rowlands_SubdermalimplantslegalJFPRHCOct2010_Uni_repos_version.pdf

Implant

Side Effects:

- Altered bleeding pattern 20% amenorrhoea,

  50% infrequent/frequent/ prolonged

http://www.fsrh.org/pdfs/CEUGuidanceProblematicBleedingHormonalContraception.pdf 2015

- Mood change
- Acne
- Loss of libido
- Headache

Implant Training

RCN no longer accredits

FSRH LoC:

- Training involves: Model arm/Local anaesthetic/ Counselling/Insertion + Removal/Side effect management
- e-learning FSRH Module 17
- Passed eKA (assessment of knowledge) or holds current FSRH Diploma (NDFSRH)
- Competent in consultation skills
- Up to date with resuscitation and anaphylaxis – in accordance with local policy -including competency to give intramuscular injections

IUS - Mirena

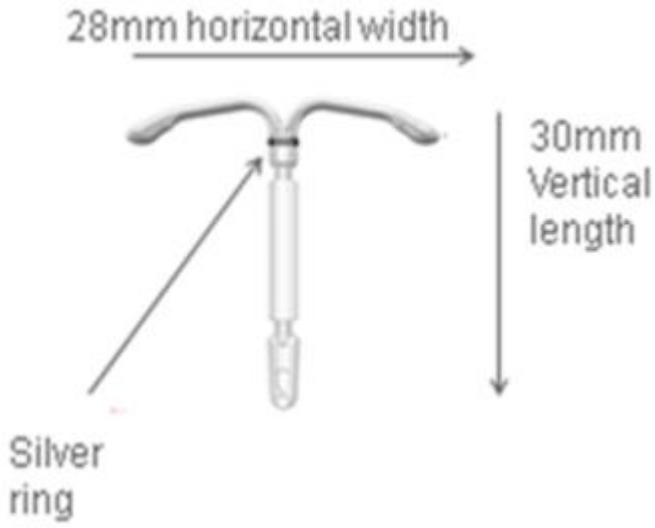
- Mirena® 20 micrograms/24 hours intrauterine delivery system
- Release of levonorgestrel is 20 µg/day then10 µg/day after 5 years
- Licenced for: Contraception (5yrs)/Idiopathic menorrhagia/Protection from endometrial hyperplasia during oestrogen replacement therapy (4 yrs.)
- Off license - ↓fibroid formation/↓endometriosis
- Induces expression of Glycodelin A mid cycle = localised inhibition of sperm /egg binding (Mandelin et al,Human Rep 1997)

IUS

- Evoinserter – one handed
- Slimmer, threads inside, cm measurements on both sides, less prep

IUS - Jaydess

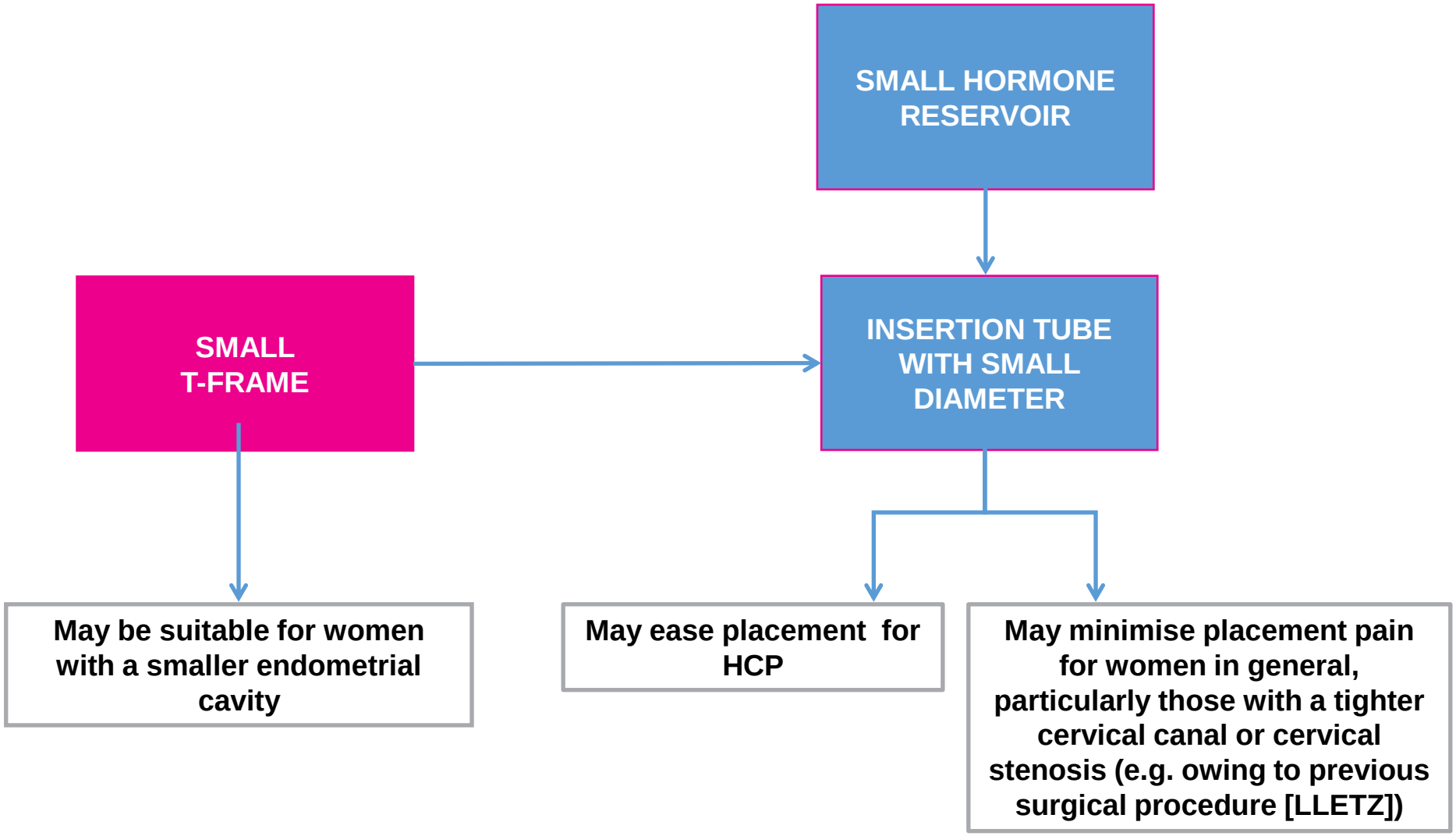
- Placed using the smallest diameter insertion tube for an IUS (3.8 mm)
- The lowest average daily dose of LNG-IUS available (6 µg levonorgestrel)
- Licensed for up to 3 years
- The world's smallest IUS



IUS - Jaydess

- The T-frames of Jaydess® and Mirena® are both visible on ultrasound
- Jaydess® has a silver ring just below the transverse arms that allows it to be distinguished *in utero*
- Jaydess® is contraindicated in women with known hypersensitivity to silver

IUS - Jaydess

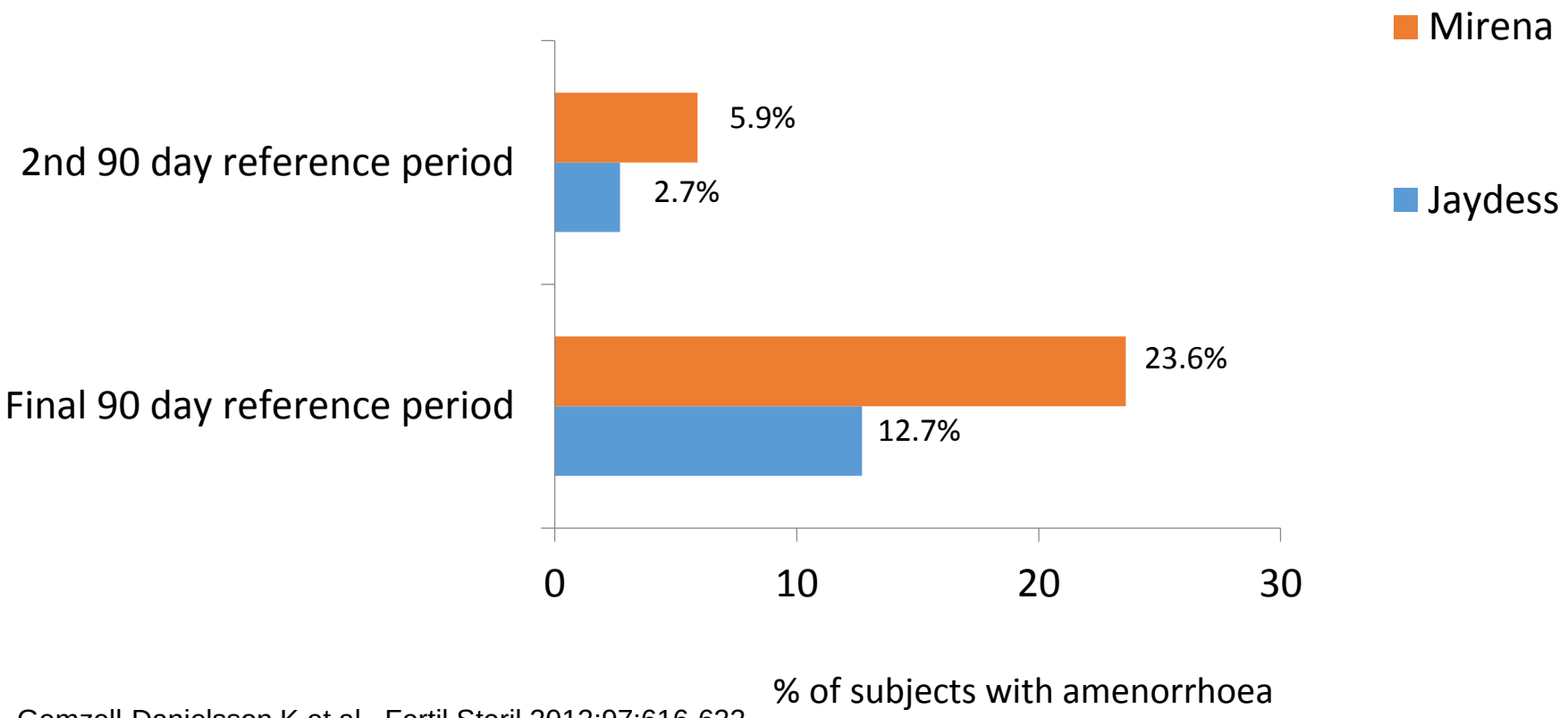

SMALL HORMONE RESERVOIR
SMALL T-FRAME
INSERTION TUBE WITH SMALL DIAMETER
May be suitable for women with a smaller endometrial cavity
May ease placement for HCP
May minimise placement pain for women in general, particularly those with a tighter cervical canal or cervical stenosis (e.g. owing to previous surgical procedure [LLETZ])

IUS - Jaydess

- Efficacy of Jaydess® is unaffected by age, parity, and body mass index
- A LNG-IUS that releases a low daily dose of LNG may result in lower systemic exposure
- For women who prefer to retain menstruation, the likelihood of amenorrhoea is 11.6% after 3 years of use
- In the unlikely event that a woman becomes pregnant while using Jaydess® there is an approximately 50% chance that the pregnancy will be ectopic
- Efficacy of Jaydess® is unaffected by age, parity, and body mass index

IUS – JAYDESS vs MIRENA

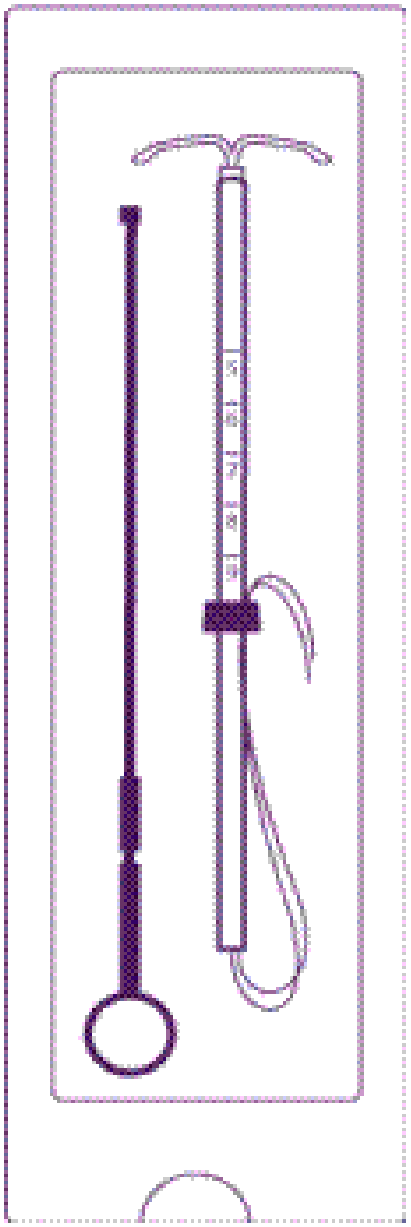
Amenorrhoea Rates

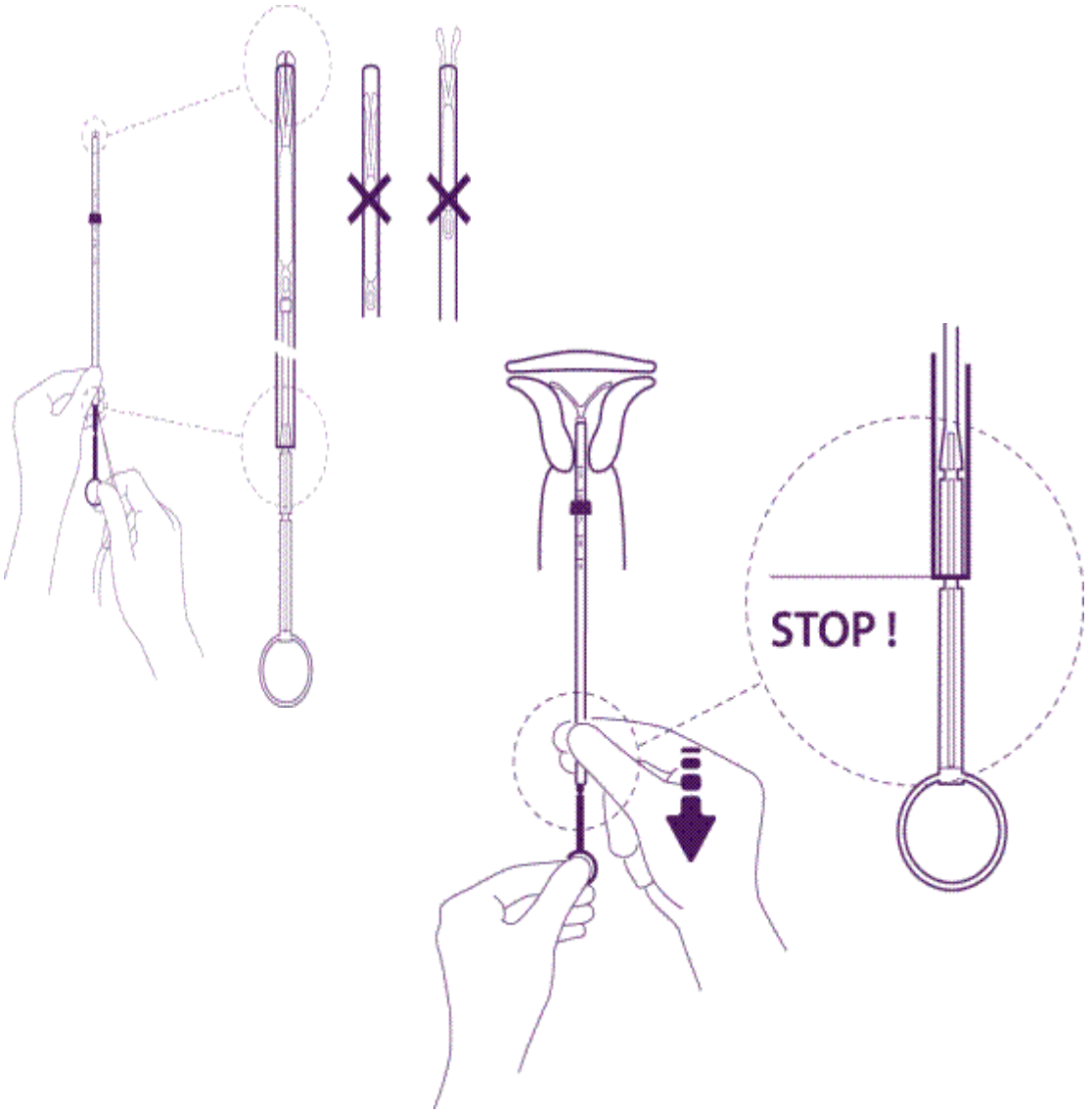


Gemzell-Danielsson K et al. Fertil Steril 2012;97:616-622

Levosert® IUS

- Levosert 20 micrograms/24 hours Intrauterine Delivery System
- 52 mg levonorgestrel
- initial release of levonorgestrel approximately 20 micrograms per day reducing to approximately 12 micrograms per day after 3 years
- licensed for 3 years for contraceptive use
- not licensed for endometrial protection
- Levosert introducer diameter is 4.8mm, compared with 4.4mm for Mirena®
- (FSRH) recommendations for Mirena® would apply when inserting Levosert®
- inserted using a two-handed technique, with a similar introducer to copper IUDs such as the UT380 and Nova T
- according to FSRH Levosert® does not appear to confer any additional benefits over Mirena® LNG-IUS
- price £66 plus VAT for 3 years (NHS price for Mirena® £88 for 5 years)
- BLUE threads!!




STOP !

IUD

- Gold standard Cu TT380, TCu380S = 10yrs
- Range of others: Mini TT380 slimline = 5yrs
  Flexi T380
  UT380 standard
  UT380 short
  Nova T380
- No less than 380Cu, multiload not recommended
- Many women with 3 yr IUD fitted elsewhere

IUT

RCN no longer accrediting nurses

FSRH Loc IUT:

- Training involves: theory/IUT/local anaesthetics and analgesia/counselling/practical training
- e-learning with FSRH Module 18
- passed eKA (assessment of knowledge) or holds current FSRH Diploma (NDFSRH)
- competent in consultation skills
- up to date with resuscitation and anaphylaxis – in accordance with local policy -including competency to give intramuscular injections
- prescriber or have access to Patient Group Directions (PGDs)
- Gynae skills

IUT

Gynaecological skills:

- Assessment of size, position and mobility of the uterus.
- Assessment, investigation and management of potential IUD/IUS users with:
  - Abnormal findings at pelvic examination
  - Heavy and/or painful periods
  - Infrequent and/or absent periods
  - Vaginal discharge and sexually transmitted infection
  - Acute and chronic pelvic pain.

- The primary trainer must be satisfied that trainees fulfil these competencies before undertaking training. Nurses should be competent to the level required in parts 1 and 2 of the RCN Genital Examination in Women
- “Trainees who lack the necessary competencies should be referred for further gynaecological experience before commencing or resuming training”

DepoProvera™

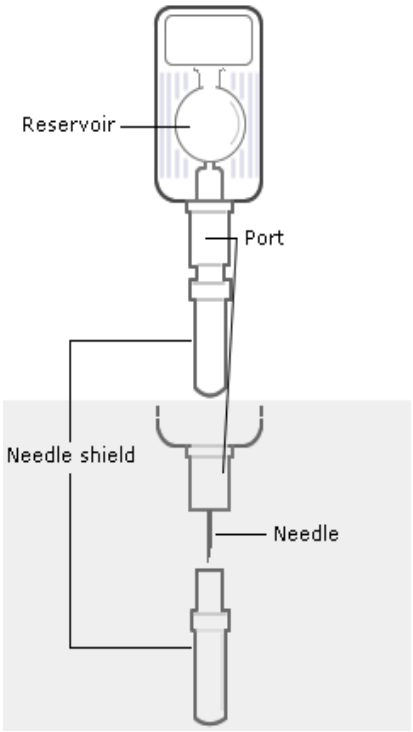
- DMPA is formulated for deep intramuscular (IM) injection as Depo-Provera™: 150mg medroxyprogesterone acetate in 1ml
- usually administered into the UOQ of gluteal muscle (do not massage)
- kept at room temperature
- given every 13 weeks (this is CEU guidance and outside the product licence for Depo-Provera™ which states every 12 weeks)
- UK guidance states that can be given late: up to 14 weeks without the loss of contraceptive cover or the need for extra contraceptive precautions (WHO = 16/52!!)

Sayana Press™

- 104mg MPA in 0.65ml in a pre-filled injector for subcutaneous (SC) injection
- injected into the anterior thigh or the abdomen avoiding bony areas or the umbilicus
- kept at room temperature
- given every 13 weeks
- women can self-administer after the first dose following training (resources to support this are available http://www.sayanaanswers.co.uk/guide-to-self-injection) under the supervision of an appropriate healthcare professional
- can be given up to 14 weeks without the loss of contraceptive cover or the need for extra contraceptive precautions

Sayana Press™

- single dose container which is activated by squeezing the needle shield and the injector port together
- before use shake vigorously.



Noristerat™

- Norethisterone enanate, or NET-EN 200mg intramuscular injection
- lasts for 8 weeks (given up to 10 weeks without extra precautions)
- licensed for short term contraception - 2 doses only in UK but may be used long term (unlicensed)
- Different BMD risks
- FSRH missed injection guidance

Bones

- small loss of bone mineral density (BMD) associated with DMPA
- maximal at 1-2 years recovering after discontinuation
- with prolonged use, the loss may be greater and take longer to recover
- no evidence of the development of osteoporosis or increased fracture risk
- caution is needed in women ≥45 years and those younger than 18 years of age (UKMEC 2)
- women aged under 18 years progestogen-only injectable contraception can be used after consideration of alternative methods
- advised that the risks and benefits of progestogen-only injectables should be assessed every two years
- switch to another method at age 50 years

Bones

Problems:

- Women on long term anti-epileptic medication (carbamazepine, phenytoin, primidone or sodium valproate) particularly if they are immobilised for long periods or have inadequate sun exposure – NICE recommends Vitamin D supplementation
- HIV+ women prone to having a lower BMD and osteopenia

Injectables - Problem Bleeding

- Rule out STI's and gynae pathology
- COC (cyclically or continuously) for 3/12
- or mefenamic acid 500 mg TDS for five days
- ??? how long for…….
- potentially bring forward date of next injection (up to 2 weeks)
- give in correct place for IM DMPA

Injectables – Drug Interactions

- no effect on the efficacy of progestogen-only injectables by liver enzyme-inducing drugs
- may reduce the efficacy of Ulapristal emergency contraception (UPA) so **DO NOT** start for **5 days** and then use extra precautions until Depo effective (extra 7 days)

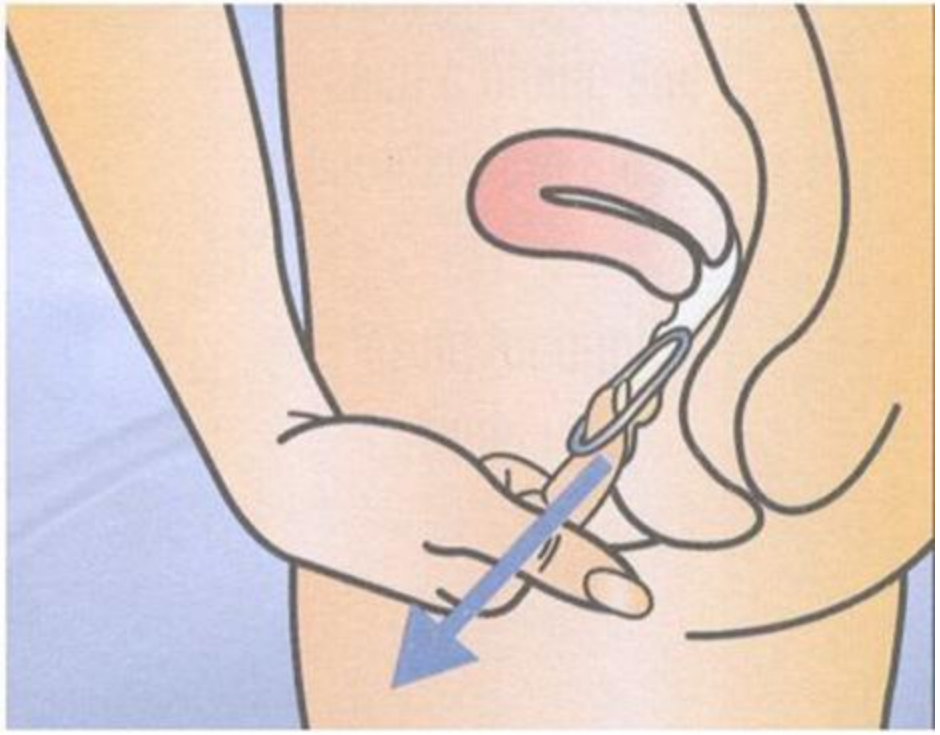
What to do if she's late????

Over 2+ weeks late:

- **Assess risk of pregnancy** (timing of sexual intercourse (SI), use of condoms, assuming contraceptive cover until 14 weeks)
- Does she need a pregnancy test?
- Assess need for emergency contraception
- If there is a low risk of pregnancy, check how she would feel about either of the following options:
- Being given DMPA (+/- emergency contraception) now and returning for a pregnancy test (PT) in three weeks
- Waiting and abstaining from SI until three weeks after last unprotected sexual intercourse (UPSI) and then having PT and DMPA
- **Amenorrhoea/timing of DMPA injection**
- Is she amenorrhoeic? Was last DMPA given on time? Is that information recorded?
- **Medical history**
- Are there any changes in her medical history?

Injectable - Checks

- Every 2 years discuss osteoporosis risks (heavy smoking, history of anorexia, low BMI, family history, diet, sunlight/vit D, oesteo-arthritis etc)
- No need for BP or weight checks at every visit unless predisposing issues – opportunity for healthy lifestyle discussion instead!!



CHC

- No longer antibiotic interaction (only enzyme inducers now)
- Missed COC pill advice changed 2011
- Off licenced use of COC for bleeding control
- VTE risks new discussion of real risks!!
- Which pill??
- Multiple choices of COC – 8 for EE and LNG alone!!
- Pill checks – who should do them??
- Pill regimes

CHC – Update on Risks!!

- VTE – smoking, obesity (BMI 30-35 x 2; >35 x 4)
- Ischaemic Stroke - migraines

CHC – Risks!!!

Venous thromboembolism (VTE)

	Risk of VTE per 10,000 healthy women over one year
Non contraceptive users and not pregnant	2
CHC containing ethinylestradiol plus levonorgestrel, norgestimate or norethisterone	5-7
CHC containing etonogestrel (ring) or norelgestromin (patch)	6-12
CHC containing ethinylestradiol plus gestodene, desogestrel or drospirenone	9-12

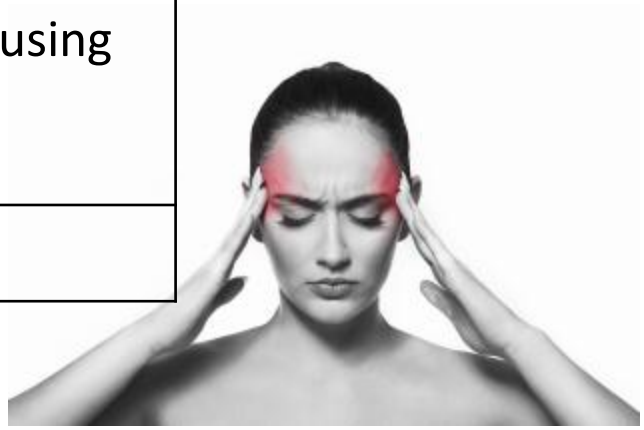
VTE risk associated with pregnancy and the postpartum period (29 per 10, 000 woman-years and 300–400 per 10,000 woman-years, respectively)

CHC – Risks!!

Migraine:

- Migraine with aura is also an independent risk factor for ischaemic stroke

UKMEC	**Risk of Ischaemic Stroke**
UKMEC 3	•Past history of migraine ≥ 5 yrs ago with aura •Migraine without aura develops while using the CHC •History of cardiovascular accident
UKMEC 4	Migraine with aura



CHC – Risks!!

Migraine with Aura Definition:

- an aura may be a visual, sensory, speech and/or motor disturbance. An aura usually precedes the headache, lasts for up to 60 minutes and resolves before the headache starts. 99% of auras are visual disturbances such as: loss of sight (e.g. haemianopia, amaurosis, tunnel vision), and/or fortification spectra (bright scintillating angulated light enlarging from a bright centre on one side to form a C-shape surrounding area of lost vision). An aura is **not** simply flashing lights.
- unilateral sensory aura is experienced by 31% of aura sufferers, in the form of paresthesia of the face, tongue, arm and sometimes the leg. 18% experience speech disturbance and 6% motor disturbance

Which Pills to choose????

2nd Generation safest

- levonogestrel (Microgynon 30)
- Norethisterone (ovysmen, loestrin 30/20, norimin)
- Mestranol/Norethisterone (Norinyl-1)

3rd and 4th Generation

- Norgestimate (Cilest)
- Desogestrel (Mercilon/Marvelon)
- Gestodene (Femodene)
- Drospirenone (Yasmin)
- Nomegestrol (Zoely)
- Dienogest (Qlaira)

Pills

New regimes other than 21/7

- Qlaira® (26/2), Zoely® (24/4), Eloine ®, Daylette ® (24/4)

Can have a tailored regime!

- Cochrane review (A) has concluded that continuous dosing/extended regimens are a reasonable approach to CHC use
- enable women to eliminate or reduce the frequency of their withdrawal bleed and any related symptoms
- an observational study (B) looking at the effectiveness of a 24/4 regimen compared with a 21/7 regimen suggests improved efficacy with the 24/4 regimen
- may wish to advise women about the use of extended or continuous regimens of CHC but use is off licence

(A) Edelman A, Gallo MF, Jensen JT, Nicholas MD, Schulz KF, Grimes DA. Continuous or extended cycle versus cyclic use of combined oral contraceptives for contraception. *Cochrane Database Syst Rev* 2005; **3**: CD004695

(B) Dinger J, Do Minh T, Buttmann N, Bardenheuer K. Effectiveness of oral contraceptive pills in a large U.S. cohort comparing progestogen and regimen. *Obstet Gynecol* 2011; **117**: 33–40

Tailored regimens for use of combined hormonal contraception (CHC)		
Type of regimen	**Suggested regimen**	**CHC-free period**
Extended use	Tricycling (3 cycles taken continuously back to back, i.e. 3 pill packets or 3 rings, or 9 patches)	7 days taken after finishing the 3rd packet, 3rd ring or 9th patch
Shortened pill-free interval	3 weeks of CHC use	4 days taken after each packet of pills, each ring or 3rd patch
Extended use with shortened pill-free interval	Method used continuously (≥21 days; pill, patch and ring-free weeks omitted) until breakthrough bleeding occurs for 3–4 days	4-day interval
Extended use with regular pill-free interval	Method used continuously (≥21days; pill, patch and ring-free weeks omitted) until breakthrough bleeding occurs for 3–4 days	7-day interval

CHC – What Examinations?

- BP and BMI should be documented for all women prior to first prescription of CHC

Blood Pressure

- systolic >140-159mmHg or diastolic >90-94mmHg (UKMEC 3)
- systolic ≥ 160mmHg or diastolic ≥ 95mmHg (UKMEC 4)

Body Mass Index

- BMI >30 - 34 kg/m^2 (UKMEC 2)
- BMI >35 kg/m^2 (UKMEC 3)

CHC – Follow up

- Follow up at 3/12 then 6/12 or sooner if any problems

Need to know:

- use of method – any missed pills, pregnancy risk, CTP detachment, CVR expulsion, late reinsertion, etc
- any changes since last visit, such as: started new medication, new partner, change or onset of migraine
- smoking history
- side effect enquiry
- cervical screening (if due)
- STI advice if appropriate
- measurement and documentation of BP
- change in weight, measurement and documentation of BMI should occur annually
- opportunity for woman to ask questions
- new supply of contraception to be given (can give 6/12 to 1yrs supply when settled on method)

POP's

- can be used until the age of 55 years when natural loss of fertility can be assumed for most women
- if they are aged over 50 years and amenorrhoeic they can continue using a POP and have FSH concentrations tested on two occasions 6 weeks apart
- if both FSH measurements are >30 IU/l this is suggestive of ovarian failure and they should continue with a POP or barrier method for one further year FSRH 2015 – March!

BUT

- NICE Nov 2015 states" Do not use a serum follicle-stimulating hormone (FSH) test to diagnose menopause in women using combined oestrogen and progestogen contraception or high-dose progestogen" ((POP does not suppress FSH (Follicle Stimulating Hormone) levels, enabling them to be used to diagnose the menopause if required)) FSRH
- "Consider using a FSH test to diagnose menopause only: in women aged 40 to 45 years with menopausal symptoms, including a change in their menstrual cycle and in women aged under 40 years in whom menopause is suspected" NICE 2015

POP's

- while a POP can be used concomitantly with hormone replacement therapy (HRT) to provide effective contraception, FSRH guidelines do not advise that a POP can be relied on as the progestogen component of HRT
- DSG pill may offer some benefits in the management of dysmenorrhoea over traditional POP's
- DSG more effective than traditional POPs and may be less likely to be associated with follicular cysts and ectopic pregnancy
- DSG appropriate for use for younger women or those with a history of symptomatic simple ovarian cysts

POP - Issues

Bleeding Patterns:

As a guide, of those using DSG-containing POPs after one year of use, approximately:

- 5 in 10 can expect amenorrhoea or infrequent bleeding
- 4 in 10 can expect regular bleeding
- 1 in 10 can expect frequent bleeding

Traditional POPs = frequent and irregular bleeding common + prolonged bleeding and amenorrhoea less likely

Mood Changes and Other Side Effects:

- mood change can occur
- acne and breast tenderness have been reported

POP – Drug Interactions

Enzyme-inducing drugs:

- increase the metabolism of POPs
- need to change to an alternative contraceptive method that is unaffected by liver enzyme-inducing drugs recommended for both short and long term use

Ulipristal Acetate (UPA):

- POPs may reduce the efficacy of UPA
- women using UPA for emergency contraception are advised not to start a hormonal method of contraception for at least five days and to use barrier methods or to abstain from sex until effective hormonal contraceptive cover has been achieved - this takes two days with POPs

Not affected by antibiotics

POP - Checks

- 1st review of the method at three months
- yearly review is sufficient in the absence of any special problems
- can supply 1 year at a time!!

Nuvaring ®

- Vaginal ring
- 15 µg/day Ethinylestradiol + 120 µg/day Etonogestrel
- 1 ring for 3 weeks/ 1 week ring free
- Similar to 30 µg COC
- Same UKMEC as COC
- Efficacy to COC
- Less BTB
- Better cycle control
- £9 a month
- Storage at room temperature for 4/12

Emergency Contraception

- Don't forget IUD – 5 days after UPSI or up to 5 days after known ovulation (day 19 of 28 day cycle)
- Levonelle 1500 microgram stat
- Or Ellaone® (Ulipristal Acetate) 30mg stat

  Within 120 hours (5 days) of UPSI

  Breastfeeding avoided for 1 week post Ellaone®

  UPA more effective than LNG

  Effectiveness reduced by enzyme inducers

  Interacts with progestogens see FSRH guidance

  Expensive £16.95

CEU would recommend that after taking UPA for EC, a woman should not start a hormonal contraceptive method for at least 5 days and be advised to use barrier methods or to abstain from sex until effective hormonal contraceptive cover has been achieved! 2015

UPA

UPA = Day 0	Methods (day UPA+5)	Requirement for additional contraception
UPA then wait at least 5 days	Combined oral contraceptive pill (except Qlaira®)	7 days
	Qlaira®) Combined oral contraceptive pill	9 days
	Combined vaginal ring/ transdermal patch	7 days
	Progestogen-only pill (traditional/ desogestrel)	2 days
	Progestogen-only implant or injectable	7 days

Barriers

New:

- one size contraceptive diaphragm (Caya®)
- no need for visit to sexual health clinic
- designed to fit most women (approximately 80%)
- pregnancy rate at 12 months of 17.8% and 13.7% with typical and perfect use
- not advised if less than 6 weeks postpartum or if previously used a diaphragm size of 85 mm or larger, or 60 mm or smaller
- should stay in situ for at least 6 hours after sexual intercourse but not more than 24 hours continuously
- available to purchase over the counter or online costs £20.54

- Reflexions® flat spring diaphragm range is being discontinued

Other Issues…….

Sodium Valporate:

- MHRA recently launched a toolkit for healthcare professionals (HCPs) regarding sodium valproate in order to communicate its teratogenic effects
- In utero exposure puts children at a high risk of serious developmental disorders (30-40% of cases) and/or congenital malformations (10% of cases)
- spina bifida; facial and skull malformations; malformations of the heart, kidney and urinary tract and limb defects. Children exposed to valproate in utero have a higher risk of autism spectrum disorders, lower IQs and developmental delays
- Female children, female adolescents, women of childbearing age and pregnant women **should not** be prescribed valproate medicines unless there is no safer alternative
- must ensure that all female patients understand the risks associated with valproate treatment and pregnancy, the need for effective contraception
- Valproate medicines do not interfere with or reduce the efficacy of any contraceptive method and contraception does not alter valproate function

http://www.fsrh.org/pdfs/CEUStatementSodiiumValproate.pdf

Coming Soon……

Nesterone® (NES/EE) contraceptive vaginal ring 1year!

- 2 ¼ inches in diameter, the ring is soft, flexible, and easily inserted into the vagina by the woman herself
- left in place for 21 days and removed for seven days, for up to 13 cycles

Nesterone® contraceptive gel/spray (Phase 1 and 2 studies)

Progesterone vaginal ring 3/12 for BF

- LNG vaginal gel – used before sex
- SPRMS Ulipristal in IUS – ↓bleeding + endometrial mitosis

Population Council - http://www.popcouncil.org/

New Male Methods

Coming soon….

Hormonal

- synthetic androgen MENT® sub-dermal implants (tissue selective, not prostate)
- Injectable stage 3 trials

Non-hormonal

- Anti-cancer drug lonidamine (antispermatogenic effects)
- Environmental toxicants eg. cadmium

TRAINING CHANGES!!!!

NDFSRH – Nurse Diploma of Sexual and Reproductive Health

- Need to be an associate member of FSRH
- Passed EKA in SRH
- Basic Gynae knowledge and skills
- Up-to-date BLS + anaphylaxis
- Course of 5
- Clinical experience – with an assessor
- Do not need to do Uni course!

e-SRH

- http://www.e-lfh.org.uk/programmes/sexual-and-reproductive-healthcare/
- e-Learning for Healthcare e-LH
- NHS e-mail address required