UPDATE ON CONTRACEPTION, Oct 2017

by John Guillebaud (JG)

<>"We have not inherited the world from our grandparents - we have borrowed it from our grandchildren" www.ecotimecapsule.com

<>"Surely, we can...get off the collision course we're on with climate catastrophe, or go down in history as a species that spent its last days monitoring its own extinction rather than taking active steps to avoid it"
Caroline Lucas, MP Green Party, 2014

<>"I have not seen a world problem that wouldn't be easier to solve with fewer people, or harder, and ultimately impossible, with more."
Sir David Attenborough 2012: Patron *Population Matters*

<>"Family planning could bring more benefits to more people at less cost than any other single 'technology' now available to the human race." James Grant, 1992: Director UNICEF

The WHO's 1-4 scale is used here as the basis for discussing eligibility, as at: www.who.int/reproductive-health The **UK version,** agreed by the FSRH ('the Faculty', of Sexual and Reproductive Health) uses notation **UKMEC 1 to 4**: see http://mag.digitalpc.co.uk/fvx/fsrh/ukmec/2016 for this invaluable resource. But here I prefer the scale **WHO 1 to 4,** since there are a few usually small differences from UKMEC, identified in below text by "[JG)" - which I feel I can justify from available evidence. More on this in the Appendix, below. Use of some brand names does *not* imply their endorsement, they are only used for ease of reference. Note also that unlicensed use of a licensed product is marked UULP throughout [NB See Glossary at end for all abbreviations]. NB: *Ultimate responsibility remains with each Practitioner, to ensure that clinical advice from any source applies in their client's case. The fpa's leaflets (pdfs) facilitate good counselling. See:* www.fpa.org.uk/resources/leaflet-and-booklet-downloads

UNLICENSED USE, LICENSED PRODUCT (UULP)

This is often termed 'off-label' or **'Named patient' use** [1-3]. Such use is needed sometimes for best contraceptive practice - whether by doctors OR nurse practitioners in SRH.
The woman should understand this course of action, though clearly evidence-based, is not yet licensed; written clarification is usual and informed verbal consent recorded.

What is required? A useful acronym is 'EG-RY-PU-RB':
1 Evidence **G**ood [best if *endorsed by a Guidance document*]
2 Responsibility **Y**ours - Pharma has no interest if not in SPC
3 Patient **U**nderstands: though *"...where prescribing unlicensed medicines is supported by authoritative clinical guidance, it may be sufficient to describe in general terms why the medicine is not licensed for the proposed use."* BUT, one ***usually*** should supply written details (eg 'take 2 pills not one')
4 Records **B**rilliant - plus Ɍ plan *communicated*, as appropriate
Ref GMC: **Good practice in prescribing and managing medicines and devices, paras 67-74**
www.gmc-uk.org/Prescribing_guidance.pdf_59055247.pdf
NB: Wherever **UULP** appears herein, it indicates *"follow completely the above good practice".*

COMBINED HORMONAL CONTRACEPTIVES (CHCs)[1,2] *The traditional COC taken 21/7 is outdated!*

The COC was devised in the 1950s. It was a unique contraceptive, the world's first ovarian suppressant. Yet John Rock with Gregory Pincus and the other pioneers supplied women with it along with a unique instruction, for a contraceptive, namely: ***please don't take it* - at all**, for a whole week, 13 times a year! Thereby regularly un-suppressing the suppressed ovary. That calamitous decision, based on the calendar and not on biochemical and ultrasound data (which did emerge, but 20 years later), permits – unsurprisingly - varying degrees of return of ovarian follicular activity during the pill-free interval (PFI).

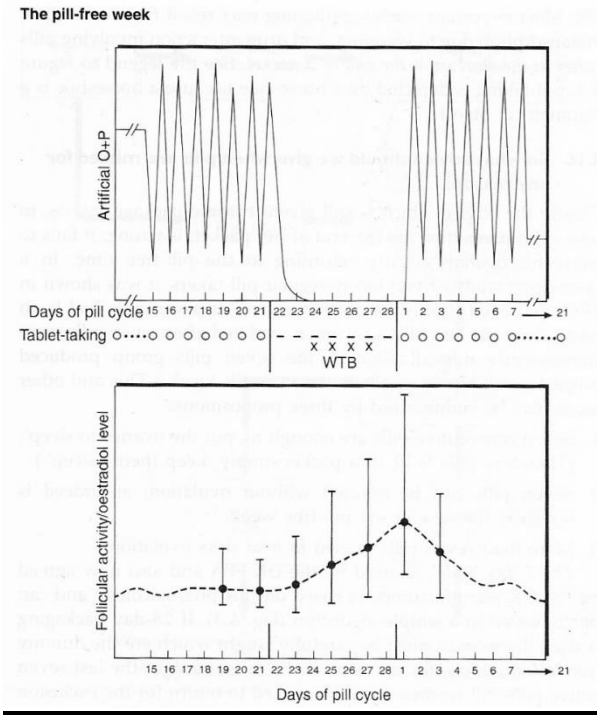

Figure 1

The top half of this image[2] depicts the daily variation in blood levels of ethinylestradiol and the progestogen after taking COC tablets, and their reduction to zero in the first days of the pill-free interval (PFI). The bottom half is based on data from the Margaret Pyke Centre (MPC) in 1978. It shows rising estradiol levels in the PFI but can equally represent, in ultrasound studies, the increasing diameter of the largest ovarian follicle. Wide standard deviations are also shown, meaning that in an important subgroup the levels are high – indeed, as high as has been observed well into the follicular phase of spontaneous menstrual cycles – implying the presence of a maturing preovulatory follicle.

In a later study at the Margaret Pyke Centre using ultrasound[4], apparently preovulatory follicles of diameter 10 mm or more were present on the seventh pill-free day in 23% of 120 pill-takers; in three women the follicle was 16–19 mm in diameter, i.e. potentially already on the point of ovulation. Such follicles grow by c 2-3 mm per day so can readily reach sizes (mean 21 mm but minimum 16 mm) associated with fertile ovulation, if the 7-day PFI is ever inadvertently lengthened. However if the PFI is shorter, ovulation must be less likely when tablets are missed after it. See Figure 2[5].

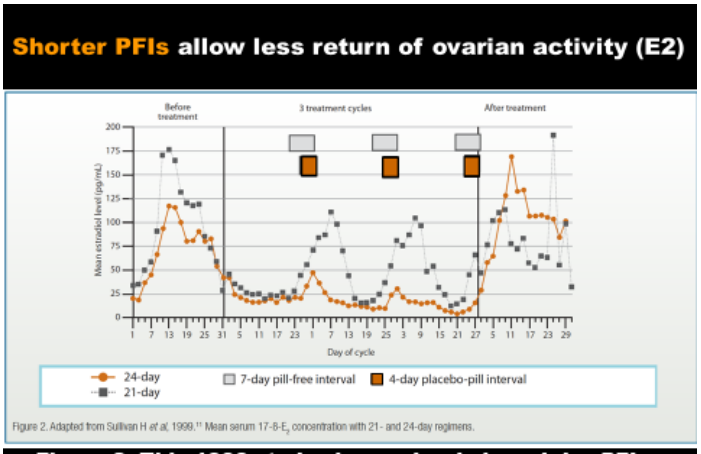

Figure 2. This 1999 study shows clearly how 4-day PFIs give no time for a follicle to grow enough to produce the levels of estradiol that presage ovulatory potential[5]

That point was convincingly confirmed by Klipping et al[6] Ovarian ultrasound scanning (Figure 3) showed 70% ovarian activity and 8% ovulation if the 7-day PFI was extended to 10 days. Of even greater interest, actual ovulation occurred in no less than 2 out of a total of 99 volunteers (two middle bars combined), with a *normal* 7 day gap ie no 'missed' pills!

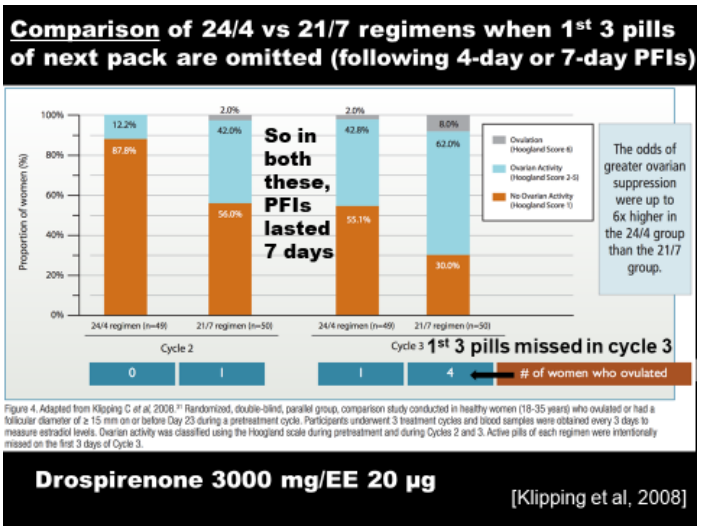

Figure 3

Figures 1-3 explain the horrendous failure rate of the traditional 21/7 COC, namely up to 9% in the first year for typical ('ordinary') users [Table 1 of reference[1]] – but also explain the 3 per 1000 failure rate among perfect-users (which without any PFIs would surely approach to zero).

But what about the adjunctive contraceptive effect of the progestogen component of COCs on the cervical mucus? Awkwardly, at the end of any 7-day PFI this hoped-for back-up will also be at its lowest ebb, it being a week since the progestogen was last ingested.

In many women, as shown in all the studies, there is no important change during the PFI, ie continuing quiescence of their ovaries. However for the unknown vulnerable minority of c 23 %[4] the Figures lead to two clear conclusions:
<> with traditional 21/7 COCs, integral to all pill-teaching should be to explain how crucial it is never to lengthen the PFI, being "the time when your ovary begins to waken up and could be nearly releasing an egg". All users should learn the *mantra*: ***I must never be a late restarter. I must never….***
<> secondly, in future, the **norm** for all COC-taking should be, surely, with PFIs that are shortened - or absent.

1. What if there were *no pill-free intervals (PFIs) at all? ie* Continuous 365/365 pill-taking[1,2].

Missed-pill advice then boils down to one instruction, simply to return to regular pill-taking. Up to 7 tablets can be missed with no more conception risk than happens 13 times a year in 'normal' 21/7 regimens! Moreover, in the studies - since 2003[7,8,9] - cyclical symptoms (those not-necessary regular bleeding days themselves, PFI-linked headaches and the PMS that some COC-users report) are all reduced. Surprisingly, very low-dose (<20µg) pills seem to work best and are already packaged that way in some markets. Edelman et al in an RCT of LNG versus NET formulations found that sustained use of a pill equivalent to UK's Loestrin 20 was the best of those tested for producing amenorrhoea[8].

Are there disadvantages or risks, if no PFIs? *Given that:*
<> there is no evidence that either the PFIs or 'pill-periods' themselves have any health advantages and
<> 365 days of 20*µg* EE pills supply *less* dose [7300 *µg*] of EE than the 8190 µg a year by 21/7 regimens using 30 µg pills, the risks should be low. (The 365/365 regimen lacks that plus point if 30 µg pills are used [10,950 µg EE/year]).
<>Moreover, to date, compared with 21/7 use endometrial, reversibility and metabolic data are all reassuring.[9]

Established or Highly Probable 'Pros' of Pill-taking 365/365 [2, 9]
(NB: most below apply also to Tricycling, including 84/4 & 63/4)

□ *Greater margin for human error.* ALL users can miss up to 7 tablets with negligible conception risk. By contrast, in 21/7 pill-taking, for the established subgroup whose ovaries escape COC-suppression fastest and if omissions lengthen the 13 annual 'contraceptively risky' pill-free intervals (PFIs): only c 1-2 tablets. Hence:

□ *Greater efficacy in typical use* despite low doses (significantly so in one study[9], an RCT with COC pills, albeit taken vaginally).

□ ***MUCH*** *less confusing 'rules' if pills are missed*: in most cases, 'Up to 7 pills missed, just restart your tablets. No extra precautions'.

□ Huge reduction in EC after missed COCs - with its added complexity if UPA used, on return to COC-taking [see p 5]

□ Vaginal bleeding (whether scheduled or unscheduled) having no known health benefits, many (not all) women appreciate regimens with *fewer total days of bleeding* per year, though with the downside of unpredictability. This is a menstrual protection advantage compared with the 21/7 regimen with its 'inevitable' 13 *scheduled* bleeds each of say 3-4 days duration. Hence:

□ *More days likely to be available for sex*, and potentially:

□ *Higher haemoglobin levels.*

□ *Reduced cyclical symptoms* for many, with *less:* –

- *headaches and migraine attacks*[9], which so commonly occur in the pill-free interval
- *menstrual pain*[9], a problem for some in their pill-withdrawal bleeds.
- *premenstrual syndrome-like symptoms*, which are often replicated on COCs when given 21/7
- *epilepsy seizures* (frequency can be reduced by steadier hormone levels) and:

□ Expected improvement in, or at least maintenance of, *known non-contraceptive benefits of COCs* [epidemiological confirmation required]: namely the reduced risk of cancers of colon and rectum, ovary and endometrium (re the latter, endometrial assessments by ultrasound and biopsy in several studies were uniformly reassuring[9]). Probably also:

□ *Improved symptoms of endometriosis* (likely, here, because of fewer bleeding days, into any ectopic endometrium).

□ *Maintained reversibility:* in one study, there was 99% return to cycling by 3 months[9]

NB: In the "tailored pill" variant of these extended use regimens[9] - see text - the woman is advised that in the event of unacceptably long bleeding/spotting, a 4 day break from pill-taking will usually produce a better bleeding pattern thereafter.

2. Tricycling[1,2] is another good extended-use option. JG now advises 84/4 ie taking 4 packets of a COC in a row, *then PFIs of 4 days* (not 7-day ones as in the US-marketed products such as Seasonale®) *for contraceptive safety* and for women who like an occasional 'period'.

These options 1 & 2 are solidly evidence-based and after all are only an extension of "running on packets for holidays" - which is already in most SPCs. Fortunately, any COC-taker may choose either 1 or 2, even now, on a UULP basis[3]. She will need warning that unscheduled bleeds and spotting may occur - esp. in early weeks. She is advised *in advance* to take a 4 day break in pill-taking[9,10] for any kind of to-her unacceptable bleeding (without extra precautions unless there have been other recent pill omissions). This provides a form of 'pharmacological curettage', after which, with resumed pill-taking, there is often acceptable oligo-amenorrhoea. This **'tailored' pill** is an empowering choice[10] for many (definitely not all) women - *and* fully supported by FSRH www.fsrh.org/documents/combined-hormonal-contraception/

The evidence-base that the 7-day PFI is contraceptively insecure is indisputable, and the manufacturers are well aware of these data. Indeed most recently marketed COC products are either packaged for extended or tricycle use - *or,* since 2000, have placebos providing PFIs of 4 days or less (ie 24/4 packaging). Unfortunately however there has been insufficient pressure on the Pharma companies from prescribers, or unwantedly-pregnant users, to change their SPCs, PILs and Pill-packaging appropriately for the *existing* established products. We badly need ALL brands to be re-packaged, with marketing authorization (which at the Regulatory authorities ought to be 'pushing at an open door') for PFIs that last no more than 4 days (using placebos as required) - or are absent altogether[2].

Fortunately, we do not have to wait endlessly for new licensing or new packs with placebos though they would be ideal. **Methods 1 and 2 can be used *now.* They should become the norm.** Each service will need to follow accurately the requirements for UULP, including *crucially* (until 'official' printed leaflets are available), supplying a dedicated patient information leaflet (PIL) - *such as one available through this author* (JG) - which explains all the above, a leaflet that:

- emphasises that though this is an ***unlicensed use of a licensed product*** it has a very strong evidence base, and is really just 'a small change to make the COC safer' and
- is supplied with the FPA's existing PIL for 21/7 regimens, with full clarity about where it differs.

5 Note also that the same arguments equally support the two available *non-oral* CHCs, the patch and ring (below), being used with patch-free or ring-free intervals that are either absent or no more than 4-days.

What about those women who continue to wish to take CHCs more 'normally' – and prefer to have scheduled withdrawal bleeds. They need to know that the latter, like normal menses indeed, have no known benefits and so can be considered completely 'optional'. *It is my belief (JG) that they will greatly diminish in number once both women and healthcare providers come to have a complete change of mindset, and cease to accept the bizarre practice of suppressing ovaries and then deliberately un-supressing them up to 13 times a year!!* But if they do not fancy even reducing their scheduled bleeds to about 4 per year by tricycling (84/4, Method 2), there is a third acceptable and currently usable option. This is the 21/4 scheme described elsewhere[2] using a reminder app (**mypillapp),** which permits setting those numbers 21 and 4 for the days of pill-taking and non-taking, respectively.

An exceedingly poor **fourth option,** surely, is to continue for another 60+ years with the less reliable, outdated 21/7 regimen, accepting thereby avoidably-high failure rates!

VTE risk, and the place of Newer COCs using estradiol: LNG/NET progestogens seem (detectably, but minimally) to *reduce* relative VTE risk, for any given EE dose[1,2]. The important 2014 MHRA 'Alert' Letter https://www.cas.dh.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102106 estimated the absolute incidence for LNG/NET CHCs as c500-700 vs in the range 900-1200 per million for DSG, GSD, DSP or CPA. Using rough point estimates of c600 vs c1000 for the mean rates, this means c400 extra cases per million users per year, and assuming 1% mortality for VTE, gives (if no other risk factor) 4 per million difference in annual VTE mortality between products using LNG/NET and those *not* using LNG or NET. *This added risk would apply if a pill taker chooses to switch from Microgynon®* to say Marvelon®, Femodene®, Yasmin® or Dianette® *but it is very similar to other risks people are prepared to take (eg on the roads, or in outdoor sporting activities).* The small risk of switching is v acceptable for *a side effect, or for acne control.* Yet it remains sensible to ***start with a LNG* or NET product**, as is usual UK practice[1,2]. [Also, for acne, to switch to the new EE 20 µg + DSP 3 mg product Eloine® – see p 11].

The new Pills (Qlaira®[11] and Zoely®[12]): would they be even safer? Probably so, since they use the *natural* estrogen E2, which though still prothrombotic is far less potently so than EE. The monthly dose is even slightly *lower* than oral HRT and there is some evidence of reduced impact on coagulation (eg lower blood levels of D-dimer than Pills with 30 µg EE). This advantage is *biologically plausible,* but as yet there is *no epidemic-ological confirmation - nor, of course, refutation* - of the hoped-for reduced venous/arterial thrombosis risk. Allowing for their high price, Qlaira and Zoely are now arguably the products of choice (JG) **IF** a woman will not accept an estrogen-free alternative method and:

<> WHO 3 applies, or she is
<> above age 45 with no risk factors, also
<> as a useful 2nd or 3rd choice of COC for side effects.

Zoely[12] has some advantages over Qlaira (JG)[1,2], including a simpler pack and the usual 7-day advice for missed pills. Both give cycle control that is OK (withdrawal bleeds can be light or absent) and, usefully, have *short* PFIs with placebos.

The 2014 MHRA alert (URL is above) includes useful printable Annexes: CHC checklist for prescribers; CHC user card; & CHC information for women. It is there pointed out that the risk of VTE with any CHC is higher:
<> during the first year of use and
<> when re-starting use after an intake break of 4 or more

weeks. This finally destroys that widespread *MYTH, that 'it's good to take a break from COC-taking after x years'!*

Transdermal EVRA®, or vaginal NuvaRing®[2,13] combined hormonal contraceptives (CHCs)

Evra patch delivers in 24 hours 33.9 µg ethinylestradiol (EE) with 203 µg norelgestromin and can be seen as *"Cilest via the skin"*. NuvaRing delivers 15 µg EE with 120 µg etonogestrel and so roughly equates to *"Mercilon via vagina"*. Hence all absolute and relative contraindications plus most practical management aspects of those COCs apply to these CHCs, which some women find easier to remember than daily pills. It remains essential never to lengthen the contraception-free (i.e. patch-free or ring-free) interval, specified for 7days as for the 21/7 COC. If this reaches 8+ days, extra precautions for 7 days are advised. The indication for EC (as for the COC) is if the patch- or ring- free interval exceeds 9 days with sexual exposure in the time since last patch or ring was *in situ*. HOWEVER, with both these CHCs, JG now advises mirroring the modern COC extended use options above and so reduce the 'margin of error' around the usage gap. Running on NuvaRings with no ring-free intervals has been described[2]. Alternatively, since its hormone content fully covers 28-plus days, an easy to remember UULP plan is to make days 1-4 of each calendar month into the regular ring-free interval (JG), so using only 12 rings per year.

Absorption problems, vomiting/diarrhoea and of course non-EID antibiotics have no detectable effect on these CHCs.

Evra: PK blood level studies of EE and symptoms suggest it is *estrogen-dominant*, and available epidemiology now suggests an increased risk of VTE compared with 30µg COCs. **Avoid use of Evra at all if body weight is >90 kg.** One-third of the few failures in the trials occurred in the 3% above that weight, which must also mean a high BMI - and the Evra blood level & VTE data just given imply it is not a good choice anyway, if there is a risk factor for VTE.

NUVARING: PK studies show lower blood EE levels than the patch so (though it also uses a '3rd generation type progestogen) a lower VTE risk might be expected: *but not yet established.* There is expulsion potential during coughing/defaecation: but only 2.3% in 1st 13 cycles, 1.7% of which were early on, during the 1st 3cycles (N=3333)[13]. *After expulsion, users may continue with the same ring after simply washing and reinserting.* Ring absence for up to 3 hours is allowed, after that condoms for 7 days are advised. *JG advises users always to check NuvaRing is in situ, as a **routine** part of foreplay.* This - plus a regular *"time for your new ring"* reminder by alarm/text messaging from one's mobile - should help to prevent post ring-free time conceptions (high risk, as there is no vaginal sensation from the ring to act as a reminder). In pre-market studies *sexual satisfaction increased or was the same in 91% of women.* With enthusiasm from the provider(s) there was high ring satisfaction even in the presence of what was termed "baseline discomfort with genital touching".

In an RCT, many more ring-users than patch users wished to continue the trial product rather than go back to a COC[13]. Usefully, *less BTB plus spotting each cycle was shown through to one year than with Microgynon*[1,2].

QUICK-START & BRIDGING[14]

Background: Traditionally, initiation of hormonal and intrauterine methods of contraception has been delayed until the next menstrual period, mainly to avoid inadvertent use during pregnancy. But that risk if a medical method is started at the time the woman is first seen can be minimized, by a careful sexual & menstrual history. Moreover, acc to WHO:

<> the risks to a fetus (ie teratogenesis) from exposure to all usual CHCs and POPs are established as negligible or absent.

<> Yet, it should be recorded that she has been *warned to stop promptly if she conceives*, ie *before organogenesis* - which occurs after the time of the 1st missed period. Ceasing then makes fetal damage even less likely, so that if this is ensured the ***provider now, with most methods, really needs to have a good reason NOT to propose quick-starting.***

<> Record also the advice: "100% follow-up to confirm not pregnant " – usually by text, email or phone (Practice Nurse) Should there be the slightest doubt, a pregnancy test now costs no more than £1 (from *Poundland*® or *Poundworld*®).

<> The main thing is that starting the new method only at the next period risks an avoidable conception *after* she was seen. WHO after reviewing all relevant data concluded this tradition potentially causes *more* morbidity via conceptions than Quick-starting or Bridging as defined at 1 & 2 below.

<> Less important, the woman is *probably* more likely to initiate the new method when seen, than at the next period.

More on quick-starting [= ref [14] with JG's adaptations] : www.fsrh.org/pdfs/CEUGuidanceQuickStartingContraception.pdf

1 If a health professional is '*reasonably sure'* (see Box) that a woman is not pregnant from recent UPSI nor on the way to conceiving (ie an unimplanted blastocyst), 'medical' methods of contraception can be started immediately ie ***'quick-started'***, unless the woman prefers to wait until her next period. Such practice for drugs or devices is usually unlicensed (UULP). The woman *must **also** receive the usual advice when starting around mid-cycle*, about abstinence or condom use for - with most hormonal methods - 7 days. ***NB: See special terms below re quick-starts after EC by UPA!***

What, according to WHO[14] (+ JG adaptations), can make a prescriber 'reasonably sure' of a conception risk that is small enough to justify quick-starting?

- 'Believable' abstinence since normal LMP
- Within [7] days [less if short cycles] of normal LMP
- Within 4 weeks post-partum (not lactating)
- Within 6 months post-partum with full breastfeeding (baby's nutrition entirely from mother) & amenorrhoeic [= LAM, 98% effective]
- Within 5 days [2nd bullet] of abortion/miscarriage
- 'Believable' consistent use of a reliable contra-ceptive (*sic acc to WHO)*, may include condoms).

Also: after hormonal EC, usually (*for details see below*) and above age 51 – terms apply, see the **Note** at end of text in older woman section, p13.

Bridging is quick-starting exactly as above, except that the woman initiates a pill (POP or COC), but plans with her FP provider, from the start, for this to be short term and to switch

later, usually to a LARC. This is generally because:
<>her preferred IUS or implant is not available that day, or
<>recent UPSI requires a -ve pregnancy test *(but in 3/52 time)*
NB also avoids the logistic nightmare of ensuring, in the real world, that fittings are only done as advised prior to Day 7!
3 If pregnancy is later diagnosed and the woman wants to go to term, any quick-started method should be ceased, ideally right after the first missed period and so before organogenesis.
4 *Avoid*, generally, these mid-cycle ways of commencing:

- anti-androgens: (DSP, in (eg) Yasmin & dienogest in Qlaira are 1/3 potency of CPA in co-cyprindiol) – because of *uncertainty re feminising of a male fetus*[2].
- LNG-IUS (Levosert/Mirena/Jaydess): if conception occurred despite using the WHO criteria, the peri-fetal levels of LNG would be worryingly v high.

Caution also with DMPA, whether given im or sc: because, unlike all other methods, once injected it cannot be discontinued. [Data do not suggest that DMPA causes birth defects, so quick-starting is not ruled out, on a case-by-case basis]. **In all these, initial bridging by POP or CHC till conception can be confidently excluded is preferable** - even ideal, making possible any-day fitting of the IUSs.
5 The copper-bearing intrauterine device may always be started immediately if the criteria for its use as emergency contraception (EC) are met, see below: with the great advantage that it also 'bridges' to the next period, with long term use to follow in suitable cases, definitely including many nulliparae. See more in the general IUC section below.
6 Immediate 'quick-starting' (bridging) with a COC or POP (eg DSG POP) is part of a most useful **protocol,** even when there *have* been UPSIs after LMP or when 'no' LMP:
<> ie after a *very overdue DMPA injection, defined by the FSRH as 14 or more weeks since last dose* or
<>during *post partum amenorrhoea.* See Box:

The *'Proving not Pregnant Protocol'* - with ongoing UPSI[1,2]
After a negative pregnancy test, **or** not done, and with or without hormonal EC as judged necessary, the woman agrees:
<> to ***bridge*** a chosen anovulant OC (DSG POP or non-anti-androgenic COC), and to take it *well*
<> with added precautions initially (eg condoms x 7 days)
<> plus to have a follow-up pregnancy test 3 weeks after last UPSI. If compliance good, a negative result establishes no conception (when first seen and more importantly, now). With confidence, can start any LARC (or *inject overdue DMPA*).
<>?inconsistent OC-taking: warn, re retest if ?pregnancy s/s.

EMERGENCY CONTRACEPTION (EC)[15]

Copper is toxic to sperm and also blocks implantation with rapid onset of the effects. Women deserve to know that immediate insertion of a copper IUD is therefore by an order of magnitude the most effective EC, **with a failure rate of c 1:1000**[16]. The potent anti-implantation effect makes it **usable – *in good faith* - for EC up to 5 days after the calculated day of ovulation. It is effective ++** regardless of the number/timing of unprotected sexual acts up to that time. This is not only legal in UK law, which since 2002 defines conception as not complete till implantation[17], but in JG's view is also ethical[18]. Therefore, if it appears that EC will be given between fertilization and implantation (not less than 5 days), the only truly effective course - despite the perceived 'hassle' for all concerned - is always Cu IUD insertion[16]. Re the fitting of which IUD and related issues, see pp 8-10.

Hormonal EC. Unlike LNG EC[19], **ellaOne® 30 mg stat** is fully licensed for use until 5 days or120 hours after the earliest UPSI. It contains **ulipristal acetate (UPA),** which is a synthetic selective progesterone receptor modulator with antagonist and partial agonist effects. It is a more potent inhibitor of imminent ovulation than LNG EC (Upostelle® & Levonelle 1500®). In a meta-analysis of 2 studies[20] it **prevented over 50% more conceptions than LNG EC, when given on any day post UPSI** - not just days 4 &5 - **IF** followed by abstinence through till the next menses.
UPA EC is more expensive for the NHS but has been shown to be ***cost effective***, through preventing more conceptions. Without abstinence the failure rate of both EC methods goes up considerably – 4-fold in the case of UPA EC: an argument at first glance for quick-starting the woman's chosen long-term contraceptive. *However, since Sept 2015, if any progestogen-containing method follows after UPA EC, there is an **important new policy,** as now explained/…:*

Which hormonal EC to use, why, and how?
1 As a progestogen receptor antagonist, it was expected that all quick-started progestogen-containing contraceptives would have their effectiveness reduced after UPA. However: www.fsrh.org/pdfs/CEUStatementQuickStartingAfterUPA.pdf explains new evidence[21,22] that weakening of such methods that *follow* UPA is NOT shown - which seems good. But there is more:
2 **UPA EC** nearly always DELAYS rather than inhibiting ovulation. Though LNG EC acts by delay less often, we should have been warning *all* EC-takers before now, *that "after working fine today, there might be a fully fertile egg released during the next week".*
3 These data at 2 seemed to reinforce the argument for quick-starts routinely after hormonal EC; that is, until a new study[22] in 2015 unexpectedly (to many) showed that, after UPA, the risk of a subsequent fertile ovulation in the **next 5 days** actually *increases highly significantly with next-day quick-starting of a DSG POP*. Sperm, from UPSI before she was seen, might easily survive in the genital tract till then.
4 The mechanism is thought to be that DSG reinitiates the ovarian progesterone receptor signalling that the antagonist UPA had blocked. There is concern (unconfirmed) that the same may well apply to all contraceptives containing a progestogen, DSG or other. Therefore, pending more data:
5 **The FSRH now (Sept 2015) advises after UPA (only):**
<> *Do not start* ANY progestogen-containing method until 5 days later with (ideally) abstinence, or condoms till then,
<> Continue the latter *for some days after the new FP method starts, as is usually advised – details at* 6 & 7 here.
6 Generally, when starting hormonal contraception later than the 5th day of a cycle, including quick-starting after LNG-only emergency contraception, the FSRH[15] advises condoms, or avoidance of sex, for 7 days for CHCs (9 days

for Qlaira®[11]), implants & injectables - but 2 days for POPs**.
7 Therefore, following those 5-days of either abstinence or barriers that is now advised after EC using UPA, extra precautions should continue for the same number of days as at 6 after any progestogen-containing method is started.
8 There's been no change in the evidence that, *provided there is no quick-started hormonal method - which will weaken UPA even for sex before presentation* - UPA EC is more effective than LNG EC. So, ***in high risk cases*:**
9 *UPA is clearly the 'stronger' EC IF* a woman accepts abstaining (ideally) for 5 days, and continues so or uses condoms, well: either until her next period, or for some days fewer if she *'semi'-quick-starts* hormonal FP after 5 days.
10 ***Otherwise,*** if it is deemed unlikely she will fully comply with the instructions at 9 above, and if the 'strongest' EC of all (*EC by Cu*) is unacceptable: 'apply clinical judgement' as the FSRH says, about using LNG EC, since this method: <>*allows next-day quick-start of a <u>new</u> hormonal method &* <>*after missed pills, permits an immediate restart - which also makes more sense to her than 9 above.*

Following earlier use of any progestogen, allow 7 days of 'wash-out' before UPA EC, to allow for long half-lives.

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**Two days for POPs is 'traditional'; but the evidence-base that this is enough time to create sperm-impermeable mucus is not very strong and there is a case for using the 7-day advice, as in most SPCs for POPs (JG)[1,2]. This may also restore the anovulation effect of DSG-POPs. (One can say 'the most *crucial days* are the first 2').

<u>Other facts about UPA EC:</u>
1 There is at least a 20% incidence of a week's delay in start of the next menses *even when the UPA EC 'works'*- no surprise given its mechanism, but must pre-warn about this…
2 The FSRH now advises this may be used *more than once* per cycle, in good faith, avoiding after possible implantation.
3 Above c 70 kg weight UPA EC was significantly more effective than LNG EC[23]. In 2017 the FSRH advice is to use UPA above 70 kg, or to double the dose of LNG EC (UULP). [**NB** efficacy reduction relates to *weight* not BMI, linked to dilution of the EC agent in *total body water*].
Any other indications? The prime mechanism of both LNG EC and UPA EC is to delay or less often prevent ovulation. They do *not* seem to cause implantation-block[15,24] at these doses. For that, always offer a Cu-IUD.
<u>Contraindications (WHO 4) to *either* hormonal EC</u> method, aside from current pregnancy, in my view, are[2]:
<>known **<u>severe</u>** allergy to any constituent of the pills
<>known **<u>acute</u>** porphyria with previous severe attack(s) induced by sex hormones.
<u>Caution (WHO 3)</u> applies *with both hormonal methods*, if the woman is on ***an enzyme-inducer*** (including St John's Wort). **This primarily indicates EC by Cu**; but if that is refused or not feasible the hormonal dose may be doubled (UULP). NB this is JG's view, the FSRH currently (2017) only supports this for LNG EC[15].
Lactation: EC should rarely ever be needed, see below, but if so either LNG EC or a Cu IUD is preferable. (If UPA EC is used, the SPC advises expressing breast milk for 7 days).
Other **C-Is** are in UPA's SPC at www.medicines.org.uk/emc

<u>POST PARTUM CONTRACEPTION</u>[1,2]

After delivery, with or without breastfeeding, 'quick-starting' is a good option for ALL methods except CHCs www.fsrh.org/standards-and-guidance/documents/contraception-after-pregnancy-guideline-january-2017 (UULP applies), though IUCs in UK are usually inserted after 4 weeks. With no breastfeeding, the earliest likely ovulation is on Day 28, hence all hormonal methods (CHCs, injections, implants and the LNG-IUS) are effective if started that day; or 7 days earlier to allow full contraception to develop without needing added precautions. Day 21 for CHCs also allows for post partum VTE risk (WHO 2), but delay until Day 42 if an added *VTE risk factor* is present. If women having UPSI request contraception later, even much later, with continuing amenorrhoea, one can use the protocol of the Box on p 5.

<u>Emergency contraception:</u> for a non-lactating woman with post partum amenorrhoea and continuing UPSIs, offer either LNG EC or UPA EC as appropriate and with the now-advised instructions about the new FP method to follow (see points 9 & 10 in the EC section). After that, use the *'Proving not Pregnant Protocol'* (Box on p 5), a much better bet than the too-often-given advice *'use condoms until your next period'*…. which maybe never comes!

<u>Lactation</u>[1,2]

CHCs should not be used pre-Day 42 since they can suppress lactation and are needlessly strong if LAM applies – see Box.

<u>Criteria for contraception by the Lactational amenorrhoea *method* (LAM)</u>
<> Amenorrhoea, since the lochia ceased
<> Full lactation—the baby's *nutrition* is effectively all from its mother, sips of water only allowed
<> Baby not yet 6 months old
If and only if all 3 of these are true, this method is 98% effective to 6 months - and v close to 100% if POPs added.

LAM is among the *recommended* 'natural' methods[25]. There is much more on all these at the superb URL www.fertilityuk.org, also at www.fsrh.org/pdfs/CEUGuidanceFertilityAwarenessMethods.pdf

POPs including DSG POPs: started at Day 21 - or (like Nexplanon below), could be at any time up to then after the birth - are the first-choice hormonal method in lactation and no added precautions are advised. So effective is that combination that EC is very rarely indicated for missed POPs. But because breastfeeding varies in its intensity, if an old-type POP tablet (not the DSG POP) is 3 hours late it is still 'traditional' to advise additional precautions during the next two tablet-taking days. Beware of the loss of POP efficacy as, in due course, diminishing breastfeeding ceases to make up for likely less-than-perfect POP-taking: a possible reason for choosing a DSG POP in lactation. Otherwise, consider providing a CHC or a LARC in advance of weaning.
Nexplanon uses the same hormone as the DSG POP and is similarly usable from day 1 after delivery, with some expectation of acceptable oligo-amenorrhoea to follow: cf insertion at other times.

IUDs and the LNG-IUS are insertable from 4 weeks; but should be deferred (WHO 4) if there is puerperal sepsis, or in trophoblastic disease with persistent urinary hCG.

PROGESTOGEN-ONLY PILLS (POPs)[1,2]

The DSG POP® is available in many brands including Cerazette® and contains desogestrel 75 µg. It blocks ovulation in c 97% of cycles, plus the usual mucus-block as back-up: hence 'perfect-use' efficacy is better than any previous POP studied, Pearl Index 0.17 (CI 0-0.9). 'Typical use' is not well-studied: but an anovulant method that lacks a PFI to weaken it has an inbuilt advantage. So this is appropriate for any young woman, *without* necessarily first trying the COC. It is a good option if the COC is WHO 4 or 3: eg often in structural heart disease: or a history of or impending high risk of thrombosis – such as to cover major or leg surgery; or (unlike other POPs), a past ectopic. Old-type POPs have very adequate effectiveness in low fertility states eg above age 45 and during breastfeeding.
Unacceptable irregular bleeding may occur with the DSG POP early on, usually but not always improving: at one year 50% have oligo-amenorrhoea. If unacceptable bleeding continues and no unrelated cause such as *Chlamydia* is found, taking 2 tablets daily (or maybe better, one bd) is worth a trial (JG): but there are no studies and it is UULP.
Moderate obesity: *no current concerns re lack of efficacy*. Case reports give a little support (JG) to taking 2 tablets daily IF weight *above 100 kg* (not lower, & this is UULP).
POPs and hepatic enzyme inducer drugs (EIDs): to give two DSG POPs while on EIDs is logical[1,2,26]. JG suggests one tablet bd. This doubling is UULP, not advised by the Pharma companies nor, as yet, by the FSRH.
Missed DSG POP pills: 12 hour leeway in pill-taking is now approved, before extra precautions are advised[2] - but, for ALL POPs (DSG POP included), the FSRH advice is that these need only be for 48 hours after restarting the POP tablets - preceded by EC if there was any UPSI while the POP-induced mucus block to sperm was lost. [NB: see JG's POP footnote on p 6; here again it may be prudent to give, as the SPCs do, the more cautious advice, namely 7 not 2 days' added contraception prior to expecting full efficacy].

LONG-ACTING REVERSIBLE CONTRACEPTIVES[27]

IMPLANTS: **Nexplanon**®[28] has replaced Implanon, since November 2010. It is a single 40 mm x 2 mm subdermal rod releasing etonogestrel (the biologically active metabolite of desogestrel) over 3 years, and differs from Implanon ONLY by containing some barium, so it is radio-opaque. The new applicator is designed to make it more difficult to insert Nexplanon too deeply. There is an online-based training including Module 17 accessed through www.fsrh.org. E-training for clinicians (*nurses or doctors*) must be supplemented by hands-on insertion experience using model arms, followed by supervised live patient training and then by doing at least 12 insertions per year.
Use minimum LA so as not to mask palpation of successful insertion, or the option of ethyl chloride spray [Cryogesic®].[2]
Efficacy: aside from abstinence and vasectomy, the failure rate of Nexplanon (c5:10,000) is unmatched - if insertion is not in a conception cycle. *Indeed it often helps to avoid the latter risk through a routine policy of initiating an anovulant method at counselling, to* ***bridge*** *to the time of Nexplanon insertion* and normally 'overlapping' with it[1,2].
Unacceptable bleeding: Unacceptable frequent or prolonged bleeds affect around a fifth of users at one year. Forewarning with reassurance is crucial. Pre-existing amenorrhoea may help, eg during lactation. See below re a way of *hopefully pre-empting this problem through a policy of preliminary DMPA, long enough to cause amenorrhoea.*
With both **DMPA** *(below) and* **Nexplanon**: first, by using a modified version of JG's **'D-Checklist'** for breakthrough bleeding [see Appendix], eliminate an unrelated cause for the bleeding, such as **D**isease (eg Chlamydia) or **D**rugs (EIDs). Then try (the evidence gets weaker lower down the list here):
1 **3 cycles of EE** via any suitable 20-30 µg COC. This usually controls the bleeding within a week while the tablets are being taken, accompanied by monthly shedding of the woman's spotting-prone endometrium through the 'pharmacological curettage' between packs. Thereafter the woman may obtain (not invariably) what she considers an acceptable bleeding pattern - though she should be pre-warned that it is unlikely to be so good as during the short-term COC. The latter treatment is *repeatable prn* while retaining the Nexplanon; or with DMPA, though there is a useful alternative, namely to give doses every 8-10 weeks.
2 Should the COC be WHO 4 for the woman, try **mefenamic acid 500 mg twice daily** or naproxen 500 mg bd for 5 days or longer with clinical judgement. There is some RCT support for the former NSAID[2], mainly for stopping a particular long bleed.
3 Another possibility which seems to help in some cases but is NOT well evidence-based is to give **added oral progestogen** (UULP) eg a daily oral DSG POP tablet or provera 10 mg 8-hourly. Incidentally, NET is *not good* for this use (nor for postponing periods): the SPC warns of VTE risk, each 1 mg of NET being metabolised to c 4 µg EE !! Now preferred is to use MPA (Provera®) 10mg 8-hrly.[29]
Always consider, also, the option of switching altogether, to *another contraceptive – maybe Jaydess®, see below.*
Nexplanon and EIDs: The SPC reports that these lower the blood levels of etonogestrel and conceptions have occurred. Therefore avoid this method if long term EID treatment is planned (eg in epilepsy). Women on *short term treatment* with one of these drugs are advised to use a barrier method also and (because reversal of enzyme induction is slow) for 28 days thereafter. During *long-term EID treatment*, MSD (Pharma) recommends transfer to an unaffected method. Given that ***EID users do very well with DMPA or an IUS or a Cu IUD*** (see below), these are definitely preferred.
Bone density: unlike DMPA, pending more data there are *no current worries here re bone density*. (See below).

INJECTABLES

DMPA, given as Depo-Provera® im[30] **or Sayana Press**® sc.[31]
Normal dose of the former is 150 mg im, every *12 weeks*, though interestingly in many countries the usual frequency is 13-weekly, which is the same as, now, the 104 mg sc dose of **Sayana Press**[31]**.** This DMPA product is almost the same price as 'Depo' and *everything about Depo-Provera also applies to*

Sayana Press: except of course *the different instructions for the injection process, explained for both providers and users in a most helpful 7-step animated film on Pfizer's website* www.sayanaanswers.co.uk/guide-to-self-injection
The subcutaneous route into abdomen or anterior thigh:
<> is advantageous in gross obesity
<> minimises haematoma risk for those on anticoagulants, and
<> has the potential for self-injection (approved in Sept. 2015).
This last makes it more practical to implement for DMPA **the elimination of *routine* follow-up visits,** as indeed is now recommended for most methods. WHO and the FSRH recommend that, instead of these, there is a truly **'Open House' policy** for all healthy, normotensive users of hormonal contraceptives, including injectables all the CHCs, POPs and Nexplanon – and IUCs, see below. **'Open House'** ensures that users who have any concerns about their method are seen promptly, at any time after its initiation, *upon request*.
New users of injectables: The *unique features* should be discussed with new users of both these forms of DMPA, namely: (a) once injected it cannot be removed; (b) it causes delay in return *(but **no** loss)* of fertility; and (c) it is truly capable of causing the weight gain for which it is blamed (not proven for any other hormonal method): a mean of c3 kg in 2 years [in a Cochrane review][2]. But weight gain is ***not*** certain for every case, the problem can be pre-empted by forewarning and advice! *Forewarn also* about the likely irregular bleeding: if it occurs, unacceptably, see at **Nexplanon** above.
Also, when given **subcutaneously** rather than im, *warn that* **skin reactions,** eg irritation, induration & fat atrophy, are commoner. These can be minimised by varying injection sites.
Grossly overdue injections with continuing UPSI? See the *'Proving not Pregnant Protocol'* in Box, page 5, with refs 1-2.
Drug interactions? **NB**: in a DMPA study[32] there was 100% clearance from the blood by the liver, specific to this progestogen. DMPA either as an im or sc depot, is therefore an **excellent choice for women on *enzyme inducer drugs (EIDs)***, since they cannot increase this already 100% clearance. Hence both Pfizer and FSRH/UKMEC advise no change in the usual injection frequency during EID use.
How long to use DMPA? given the ongoing concern about low estrogen reducing bone density, in a minority. If this occurs, there is evidence of reversibility both in younger and older women; but uncertainty persists[1,2]. **In summary**: The protocol introduced after the MHRA circular (18/11/2004) requires *"careful re-evaluation of risks and benefits"* every 2 years, comparing with other options in the fpa's excellent "*Your guide to contraception"*.
For the few young women with known risk factors for osteoporosis already, DMPA is WHO 4, maybe 3.
Under age 18, due to concern that it may - mostly reversibly - reduce achievement of peak bone mass, UKMEC classifies DMPA as WHO 2; and the UK advice since 2004 is it is fine to use first-line in teens "but **only** after other methods have been discussed" and are unsuitable or unacceptable. DMPA is also WHO 2 above age 45, for obvious reasons.
In sum, DMPA is very useful though (now) being seen as a relatively short term method, after which switching to another method is usual. A good choice then can be Nexplanon, which for a user is a bit like DMPA with one's injection 3-yearly rather than 3-monthly... For teens and indeed others, JG's suggested routine policy with implants is to plan to use DMPA first. Oligo-amenorrhoea is established usually well within 1-2 years, aided if needed by giving the injections 8- or 10-weekly (UULP). There is then a good chance (but no certainty) this will be maintained after the Nexplanon is inserted: thus hopefully pre-empting Nexplanon bleeding problems… Moreover the insertion can then be at any time: no fear of an insertion-cycle conception…. Another 'plus' is the shortish duration of DMPA use, meaning less weight gain concerns.
If the woman wishes to use DMPA for **much longer than 2 years,** it is as always her right to decide to do so, after counselling about the uncertainty. This should be ***with*** continuing 2-yearly reassessment of alternatives ***but without bone scanning or blood tests unless clinically indicated,*** for that woman. NB: Being estrogen-free, DMPA is objectively *safer*, overall, than any CHC as an alternative.
Same problem with long term Nexplanon? No, the data are reassuring there so far, re both estradiol levels and bone density: in comparative 2-yr. studies both remained closely similar to those in copper IUD-users[28]. By analogy, no worries on this issue with the DSG POP either - nor with the LNG-IUS, whose contraceptive actions are primarily at the uterus anyway, not the ovary.
Is HIV transmission increased by DMPA?
A 2015 meta-analysis of studies is discussed by FSRH at www.fsrh.org/pdfs/CEUStatementDMPAandHIV.pdf
Causation remains uncertain: higher coital frequency and less condom use by DMPA-users probably explain the association. WHO & FSRH agree that in an informed woman the benefits of DMPA for women at 'high risk' of HIV infection outweigh the risks (WHO 2). Both bodies stress the need for all women at risk of HIV to use condoms, along with DMPA or other methods.

INTRAUTERINE CONTRACEPTION

This means IUDs or IUSs, generically IUC. Not '*coils*' a word which can be off-putting, a bit scary!
Can be seen truly as 'reversible sterilization.'[1,2, 33-36] See p 10
The *banded* T-Safe Cu 380A IUD is in the 'gold standard' category, ie first line unless an alternative indicated. In UK they are marketed as TT 380 'Slimline' (Durbin) or T-Safe Cu 380A QL 'Quick Load' (Williams Medical) see MIMS. *This banded type of IUD should be one's first choice*, given its effectiveness which is nearly, not quite, that of the LNG-IUS. The *main* advantage over wire-only IUDs is *not* just its greater efficacy[36] but its licence for at least 10-years *in situ* - and research in the past 50 years has so clearly shown that most IUD complications can be (re-) insertion-related. They also reduce in frequency with greater duration of use.
NB: *Forget the myth!* Nulliparity is *not* WHO 4 for IUCs!
In mutually monogamous relationships intrauterine methods should be seen as WHO 2, rarely 3, and *suitable for a trial* with (as always) later removal as an option. **There is now a Mini TT 380 Slimline (Durbin),** usefully smaller, making it *the first-choice IUD for many nulliparae*, but still banded. It has exactly the same amount of contraceptive Cu. Hence like T-Safe Cu 380A it is usable for 10 years (UULP).

Duration of use: UK practice since 1990 is that ANY *copper IUD fitted above age 40* can be used - given declining fertility thereafter - *for the rest of reproductive life*.
When to use other IUDs? In a RCT the **Nova T380** which has *copper wire but no bands*, was effective but less so than the T-Safe Cu 380A (cumulative failure rate at 3 years 3.6 vs 1.7)30[36]. The **UT 380 Short** (Durbin) is Nova T style, with a similar finer insertion tube and licensed for 5 years, but on a shorter stem, useable for cavities down to 6 cm on sounding. In my view (JG) this is probably the next best choice in nulliparae - eg for EC - if there are actual or anticipated technical problems in fitting the banded **Mini TT 380** above. The insertion tube of the **Flexi-T 300/ Cu-Safe T300** is exceptionally small with an easy push-in fitting technique and no separate plunger. But it has a high-ish expulsion rate, is not banded and licensed for only 3 years. If bleeding or pain are later problems with any IUD a LNG-IUS may be substituted [1,2].
[Note: the Multiloads - and despite being banded, the **Flexi-T+380** - do not have any established advantages].

LNG-IUS[2,35] **Levosert®,Mirena® or Jaydess®**[37]
This method "ticks more boxes" relating to the "ideal" contraceptive than any other option (JG). It also has added value: relieving PAIN[35] and/or menorrhagia, whether or not there is need for FP - facts about both symptoms that are still not widely enough appreciated! Like banded Cu IUDs, it is like sterilization for effectiveness. Therefore, when any form of sterilization is mooted, it is crucial to seek any history of heavy **OR** painful periods, maybe many years back, before the woman's long-term use of the Pill (or other hormonal contraception) improved them – see below, p 10 Col 2.
Any LNG-IUS should *normally* be replaced as licensed (Mirena®: 5 years, Jaydess® & [for now] Levosert®: 3 years).
Other differences from copper IUDs are:
1 Being hormonal it acts slower than copper and so is **not an EC method**. Given this - and the importance of avoiding exposure of any fetus to the uniquely high local LNG levels in a conception cycle, *using an anovulant method up to and overlapping beyond the insertion time* is ideal...
2 Mirena, but not Levosert or Jaydess (below) can be used as the progestogen component of fully *contraceptive* **HRT**: popular, fully licensed and, since 2013, *the FSRH endorses its use thus for the full 5 years* (but UULP).
3 Women should be warned *to expect* that they will bleed on most days in the early weeks after insertion, but that if they are prepared to wait there will nearly always be the ideal outcome, of absent or light regular bleeding.
4 Some of the LNG gets into the blood, variably between women, and can cause progestogen-related side effects such as depression (shown in a million Danish women cohort to occur with *all* hormonal methods[38]). These usually improve as levels fall, in similar timescale - coincidentally - to the 'dribbling' of para 3 above. As a v rough approximation one can say Mirena/Levosert gives the blood levels of c 3 LNG POPs a week and Jaydess (below) equates to c 2 a week.
If **unacceptable bleeding** persists, or **returns much later**, first seek another cause (the **'D-Checklist'** [see Appendix]) - including *Chlamydia* and often a U/S scan for eg a uterine polyp, or malposition - then consider early replacement.

Jaydess®[37] Launched in UK in 2014, this is a mini-LNG-IUS with a smaller insertion diameter of 3.8mm (vs Mirena 4.4 & Levosert 4.8 mm), so it is usually easier to fit through a tight cervix. It has a 3-year licence with initial release of 14µg LNG/day versus 20 µg released by Mirena, hence is likely though not yet proven to cause fewer progestogen-linked side effects. Periods are more likely to continue (although lighter than normal). A lower amenorrhoea rate may (or may ***not***) appeal to some women. Jaydess can be a good alternative to Nexplanon for young women, including nulliparae, since acceptable bleeding patterns are more likely.
When might the same IUS be left in longer?
If fitted above age 45, and longer use is requested, the NICE Guideline[27] permits for FP (but NOT as part of HRT, see above), the sustained use of the same IUS until contraception is no longer needed (UULP) - provided the woman "does not have periods with the IUS in place". ***If only for menorrhagia or pain control,*** not FP, the same IUS may of course be *in situ* for just as long as it continues to work, with one caveat (actinomycosis risk, see below).
What about LNG-IUSs and EIDs? Walli Bounds of Margaret Pyke Centre showed maintenance of *good* effectiveness in 50 users of the IUS plus enzyme-inducers (one pregnancy reported)[2]. This is biologically entirely plausible, since the LNG would still be released in high concentration ***locally,*** despite the EIDs lowering levels in the blood, and so should have its usual effects on the utero-cervical fluid and in impairing implantation. Therefore the LNG-IUS is a good alternative to DMPA (or a Cu-IUD) for women on EIDs.
PID risk? It is well established that ***neither IUDs (with monofilament threads) nor IUSs, intrinsically, increase PID risk***[1,2]**.** Yet neither can be relied on to *protect*. Moreover it is crucial to insert through a "Chinese cervix"! This is a cervix (or rather genital tract) established to be ***pathogen-free*** [see pp 113-117 of ref [1]], so far as it can ever be by screening: first a careful history for STI risk, PLUS if then indicated vulvo-vaginal swabs for *Chlamydia* – these give the greatest sensitivity, even when self-taken.[39] **IF** a negative result is not available (eg when using a Cu IUD as EC), consider antibiotic cover, eg with azithromycin 1g stat; or, if lower-risk, ensure follow-up for possible later treatment. *Routine* IUC insertions with lowest estimated risk need no screening, nor antibiotic cover.
Past ectopic? Although anovulant methods would be *even better*, the IUS and ***banded*** IUDs are **not** ruled out[2].

Some insertion-related tips for IUDs and IUSs[2] [JG]:
1 Always apply **"vocal local"**++; aka "verbal anaesthesia"! Diana Mansour [unpublished study, Newcastle] found that reported pain was least when a particular nurse assisted.
2 *When to insert?* It is a *myth* that menstrual fitting is best, indeed expulsion rates are higher then[2], unsurprisingly, given ↑uterine activity during the *heavy* days of bleeding.
3 Insertion at the time of ***surgical*** *termination of pregnancy* is *ideal* wrt pain, given the already-present good LA or GA. Misgivings about expulsion rates, infections etc are over-stated[40]. IUCs can, and indeed should, be ***offered*** **(**with easy opt-out) to all whose pregnancies end in the first trimester, since both the ***parenteral*** **LARCs seem less good** [if

initiated then, requests for repeat terminations 2-5 years later are commoner (doi:10.1136/jfprhc-2014101059)]. Indeed, with full counselling before the day of surgery and solid agreement to remove the IUC later upon request, this must be the NORM!

4 *Pre-medication* should be routine c 40-60 minutes beforehand, since there is evidence for mefenamic acid 500 mg that this helps to *pre-empt the uterine cramping pain* reported at 10 minutes after insertion[1]. Naproxen 500 mg (available OTC as Feminax Ultra®) has also been shown to help this pain, but oddly *not ibuprofen.*

5 **Some form of *anaesthesia to the cervix should be offered, to stop the*** very severe *sharp pain*[1,2] caused, *unpredictably,* in a few women by all types of holding forceps, which often then continues through the rest of the procedure. First choice is:
(a) Lidocaine 10% spray at least 3 minutes ahead, which when applied as 3 puffs to the cervical surface and one into the external os was significantly effective, in an RCT.[41]
(b) Second choice now (2016) is *slow* inj. 2 minutes ahead of 1 ml of *warmed* LA, through a tiny needle at 12 o'clock.

6 Re Instillagel® 2% LA gel using Instillaquill via Cx: the best studies strangely fail to show significant pain relief[42]. That was shown only with a stronger (lidocaine 4%) gel, not yet marketed[42]**.** IF the 2% gel is used, instil it *slowly* and ***wait*** *at least* 3-minutes. **But JG advises, normally, only to use 10% lidocaine by spray along with premed** [as at 4 & 5(a)].

7 Paracervical LA injected at the level of the internal os is not necessary, routinely, but is effective[42] and should be used[2] if, rarely, the cervical canal needs dilatation to Hegar 5-6.

8 Beware: truly short cavities are rare. If the sound passes to ≤5cm it may only have measured the cervical canal.

9 Insertion is only considered complete [JG] after a satisfactory first follow-up, at c 4-6 weeks. Thereafter, however, *there should be no routine visits.*

10 **NB: ANNUAL CHECK-UPS** are redundant for IUCs[1,2], according to WHO. Visits are at a user's choice – on an ***"open house"*** *basis, always immediate if she has* ***pain*** *[this is the No.1 'Red flag' symptom, with in IUC-users a serious cause* ***(such as PID, ectopic, malposition) till proved otherwise].***
Overall, good training and attention to detail are crucial - for **all** intrauterine methods. To maintain expertise, the FSRH advises a minimum of 12 insertions per year.

FEMALE STERILIZATION[43]? - OR BANDED copper IUD? - OR the IUS? - *efficacy is similar for all!*

The Peterson et al study (1996)[1,2] showed the failure rate of *female sterilization in the USA at that time* to be 14/1000 at 7 years**– not different from the rates for the T-Safe Cu 380A and the IUS by 7 years[34]. After that there were zero further failures with this copper IUD to 10 years (and the evidence shows this is extendable UULP to 12 years).

SO, why do a surgical procedure at all in many cases, when a banded IUD or an IUS is of equal efficacy, reversible and above 40 (or 45, see above) can be seen as permanent, never needing replacement during the finite and often quite short time between ending childbearing and Nature's ('auto'-)sterilization method, the menopause?

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** In the UK, the FSRH quotes the 10 year failure rate[43] of the Filshie clip (NB this was NOT used in Peterson's series above) as 2-3 /1000; and of vasectomy as c 0.5/1000 after azoospermia.

Essure® – is an outpatient sterilization method[43] previously available mainly in private practice, in which flexible micro-inserts were placed into the proximal section of each fallopian tube. There were safety issues, but its discontinuation by Bayer in June 2017 was on commercial grounds. www.fsrh.org/documents/fsrh-and-rcog-joint-statement-on-bayers-decision-to-discontinue/ Symptom-free women may continue use of this method.

VASECTOMY – is discussed fully in the 2014 FSRH Guidance[43]. Using the much-to-be-preferred 'No-scalpel technique' and after nil sperm counts, its failure rate is 0.5-1:1000, decidedly more effective than the female procedures. But it shares a risk: when either of the couple are sterilized, unacceptable menstrual symptoms often return on discontinuation of the previous CHC or other hormonal method. This is how *"vasectomy can cause menorrhagia!"*[2] - a term which only means "not tolerating one's menses". Certainly, whenever sterilization for either gender is mooted, one should never omit to ask the woman about her periods *as they were* prior to hormonal contraception, maybe many years before. If they were troublesome (sometimes in the history she was actually put on the Pill decades earlier to control menstrual symptoms!), an LNG-IUS might be altogether better than sterilization, whether male or female.

CONTRACEPTION & MEDICAL PROBLEMS[1,2]

This is mainly but not only relevant to combined hormonal contraceptives **(CHCs).** It is impossible to list every known disease - or "dis-ease" - that might have a bearing on hormonal contraceptives and indeed for most this aspect has not been studied. What principles apply?

A/.First, is there summation? Are there disease-effects that *are additive* to known adverse effects of CHCs/the COC?[2]
In particular, does the condition or risk factor:
1 *Increase the risk of arterial or venous thrombosis,* anywhere? This includes consideration of restricted mobility even if the disease is otherwise unrelated to thrombosis risk.
2 Predispose to arterial wall disease or hypertension?
3 Adversely affect liver function?
4 Require treatment with an interacting drug (eg an EID?)
If none of the above 1-4 apply, the condition can be considered as at most WHO 2 for any of the CHCs.
If any do apply, CHC use will be either WHO 4 or WHO 3.
NB: WHO 3 always implies *'an alternative preferable'*[1-2].

B/. 2nd general principle, are the CHCs being given as therapy, not contraception alone? *The added non-contraceptive benefit* (from the CHC as therapy) *may then be held to justify some added risk affecting the woman* ie the risk-benefit ***difference*** might be judged similar to normal CHC-taking. Examples:
<>PCOS + acne yet a high BMI, or
<>Heavy menstrual bleeding + she refuses LNG-IUS. Yet, the added risk *per se* remains the same as if the CHC was not being used thus, as treatment. Hence, record this was *discussed and fully accepted by the patient.*

Acne/PCOS Acne, seborrhoea and sometimes hirsutism, with or without an established diagnosis of PCOS, may be benefited by any of the estrogen-dominant COCs, and particularly by those with an anti-androgenic progestogen.

What now re Dianette®? In 2013, after the European (EMA) review triggered by VTE concerns in France, the MHRA advised UK clinicians that the estrogen-dominant products using CPA (co-cyprindiol = Dianette® + its generic clones) and DSP (in Yasmin®) were **higher risk:** www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON287002
Yasmin is a monophasic COC containing DSP 3mg plus EE 30 µg. HOWEVER, a 20 µg ED variant **Eloine®** (EE 20 µg + DSP 3 mg), with the ideal 4 day PFI and 24 active pills, is now available[1,2]. Given its lower dose of EE, this has become, since 2016, the first choice product (JG) whenever Yasmin might be considered, with co-cyprindiol becoming second-line for non-responders. Eloine is *a possibility for empirical control of minor side effects with other CHCs*, esp. if fluid-retention-linked (DSP has a diuretic action). It is also *licensed in the US for treating **PMS*, **for which indication it should be given 365/365 (JG)** – see above p 2.
Feminisation of male fetuses has been shown (see SPC for Dianette®) in animal studies of CPA administered during embryogenesis. This must also be a *potential* risk with the other two anti-androgens, DSP in Eloine® & dienogest (used in Qlaira®[11]). Therefore, with COC products using any of these:
<> at initiation, pregnancy must be confidently excluded
<> bridge another pill first instead of quick-starting [see p 5]
<> *advise all: stop pill-taking if **any** suspicion of conception.*

Diabetes Mellitus (DM)
In general, and whether type 1 or type 2, this is always a WHO 3 *('alternative highly preferable')* condition for CHCs, given the higher circulatory disease risk even when there is no overt diabetic tissue damage (JG's view[1,2], yet UKMEC classes well-controlled diabetes as WHO 2). DMPA is also WHO 3 (JG) in DM, given its SPC that reports a 15-20% reduction in HDL-cholesterol[2].
So the **POP (often a DSG POP), an implant, a modern copper IUD, or a LNG-IUS are all definitely preferred** to any of the CHCs. These can all be started any time after coitarche in young diabetics. If CHCs are, reluctantly, used, it should be for cases with no known arteriopathy, retinopathy, neuropathy nor renal damage, nor any added circulatory risk factor such as obesity or smoking (all of which mean WHO 4) - and in my view only *if the duration of the disease has been less than 20 years.* Moreover the natural estradiol-containing Zoely[12] or Qlaira[11] are possibly safer (less prothrombotic) than products that use EE 20µg. Even these CHCs should be used with due caution (WHO 3), and with the plan to switch to a preferred method whenever acceptable; or to sterilization after all childbearing.

Migraine with aura[1,2]
Alone, this is a definite risk factor for ischaemic stroke, so WHO 4 for CHCs. However the data now suggest there is *no* clinically important added risk in *migraine without aura.*
What is aura?
Establish the **timing:** neurological symptoms of aura begin pre- any headache, typically last around 20–30 mins, max 60 mins, and resolve at about the start of the headache (which may be absent or mild). Premonitory symptoms like food cravings the day before are ***not*** aura.
Visual symptoms occur in 99% of true auras and hence should be asked about first.
Typically there is a bright loss of part of the visual field on the same side in both eyes (homonymous hemianopia) Fortification spectra are described, a scintillating zigzag line usually observed even with eyes shut, gradually enlarging from a bright centre on one side, to form a convex C-shape around the area of lost vision (a bright not dark scotoma).
Sensory symptoms are highly confirmatory, but occur in only about one third of cases and rarely in the absence of visual symptoms. Typically they come as 'pins and needles' (paraesthesia) spreading up one arm or one side of the face or the tongue; the leg is rarely affected. They are almost always positive symptoms, **not** loss of any motor or sensory neurological function (serious though that is - equally justifying stopping of the CHC, but also indicating urgent hospital referral). Disturbance of speech may also occur, in the form of dysphasia, again confirmatory of aura.
Aura *without headache* following is also WHO 4 for **CHCs**. **BUT all estrogen-free methods including all LARCs are OK for women with aura** – warn them that the headaches may persist, the switching is for greater safety against stroke - and will be somewhat irrelevant if they continue to smoke!
How to take an aura history:
Ask the woman to describe a typical attack from the very beginning, including any symptoms in the 1-hour before a headache. Listen, but it is more important to watch her carefully. **A very suggestive SIGN of true aura is if she 'draws something in the air' to one or other side of her own head** (Anne MacGregor, as discussed in ref 2).
In summary, aura has three main features:
1 TIMING: BEFORE or without headache, with duration ≤1 hour and disappearance before or at onset of headache
2 Symptoms VISUAL in 99 %, as described above
3 Description VISIBLE (patient waves, beside her head).

DRUG INTERACTIONS with contraceptive hormones
Some reminders[26,32]
<> (liver) enzyme-inducing drugs (EIDs) reduce blood levels of both EE and progestogens and have amazingly sustained action: for c 28 days after stopped!
<> antibiotics (except for rifampicin and rifabutin which are EIDs) pose *no problem*
<> in epilepsy the main EIDs are:
Phenobarbital, phenytoin, primidone, carbamazepine oxcarbazepine, eslicarbazepine, and topiramate *if daily dose above 200 µg*. Other conditions also indicate EIDs, see BNF
<> During short courses *and for 28 days after cessation,* advise an added method such as condoms.
<> For medium to long-term treatments, unless the woman is prepared to continue use of that extra method, the recommended contraceptives include, as explained above, DMPA; also Cu IUDs and any of the LNG-IUSs.
NB: *not* Nexplanon. For the (hopefully few) women who insist on staying on a CHC or POP, there is a complex second-choice option involving doubled doses, and 'tricycling' if it is a COC[1,2] with shortened PFIs, all = UULP.
Interaction the other way, affecting Lamotrigine[1,32]
COC/CHC effectiveness is not the problem, but blood levels

of the lamotrigine itself can be lowered by EE, increasing the risk of a seizure after the Pill is commenced and, potentially, if this is compensated for, toxicity during the PFI. Co-administration is possible, with caveats[1]. But all CHCs are WHO 3 here (JG): advise either an EE-free contraceptive or a different anti-epileptic regimen (JG). Data currently suggest that progestogens do not have this effect.

TEEN PREGNANCY PREVENTION[1,2]:

This is a big subject, which clearly depends on use of the most appropriate contraceptive technology, but also on *much more* than that - for which no space here. For more, please see the excellent 2010 Guidance from FSRH[44], also my own downloadable pdf about the worldwide '*Youthquake*' at www.populationmatters.org Table 1 here gives the (possibly surprising) JG **ranking of the first-choice methods, as at 2016,** for young people including teens: supported by earlier text in this document. **NB** *The user is the chooser:* one moves down the list during counselling to reach what must always be **her** choice. **Note** how the LARCs have priority in the list, and CHCs are advised in extended-use versions…)

Table 1: Prioritisation of preferred methods for teenagers

1. **Depo** im/**SayanaPress** sc acc to choice, then maybe move to Nexplanon when no more bleeding, or when she agrees.
2. **Nexplanon** or one of **IUSs**; but unless seen in 1st week of a cycle and able to fit at once, bridging first with a DSG-POP or COC and fitting 3 weeks(+) later at mutual convenience - after a pregnancy test prn…. (**See box on page 5 col 1**)
3. **Cu IUD**, probably put in as EC & often using the T-Safe Cu 380 A in 'Slimline Mini' version (p8). ?IUS later if xs bleeding
4. **20 µg COC: 365/365 or tricycling 84/4** = four 4-day PFIs/yr
5. **Any chosen COC taken 21/4** with smartphone reminders and entering the PFI days **into the app**[2] : www.mypillapp.com
6. **NuvaRing:** as at p3, ? with ring-free time 1st 4 days each month.
7. The **DSG POP:** though 'only a POP', it avoids dodgy PFIs!

<> If hormonal EC at 1st visit, use judgement to offer either the plan at no. 9 or no. 10 in the EC section here, p5.
<> Plus, outside of monogamy, advise/supply condoms for use prn *as well* and make available all 3 EC options.
<> At time of counselling for teens (or others) who request surgical termination of pregnancy, make the logical offer of IUD or IUS insertion at the procedure (p9 col 1).

Good news: there is some, re teen pregnancies. In 2012 the under 18 conception rate in England and Wales had fallen to 27.9/1000, 41% lower than 1969, with half leading to a legal abortion. However this rate continues to be, regrettably, higher than in many European countries….

CONTRACEPTION FOR OLDER WOMEN [1,2]

"Menopause is usually a clinical diagnosis made retrospectively after 1 year of amenorrhoea. Most women do not require measurement of their serum hormone levels to make the diagnosis.[45]*"* However any advice to cease contraception needs to follow one of 3 plans, which are incorporated into Table 2 here. This is based on Table 8 of the excellent 2017 Guideline of the FSRH[45] which is essential reading and readily available at: www.fsrh.org/standards-and-guidance/documents/fsrh-guidance-contraception-for-women-aged-over-40-years-2017/

<> **Plan A.** After age 50, after stopping any sex hormones: do not discontinue FP until after for the 'officially approved' one year of amenorrhoea. This is the obvious plan for deciding when to discontinue copper IUDs or condoms, since they do not hide the menses. **But what to do if the woman is on one of the hormonal methods, or HRT** (a separate issue and it is of course not contraceptive), **which mask the menopause?**

If on DMPA im or sc, or any CHC (that only being acceptable if risk-factor-free), age above 50 - the *mean* age of the menopause is c 51 years - is the usual latest time to switch to something else. The known risks though rare of CHCs go up with age, *even in totally risk-factor-free women and even if, as now seems logical for most such, they take natural estrogen* (Zoely or Qlaira). CHCs are by age 50+ also needlessly 'strong', contraceptively. The same applies to DMPA, and even during the decade 40-50 the FSRH advises that if an FSH result is >30 IU/L (NB it should be done just prior to next injection), it is clinically significant so can be followed by FP (any method) for just one year. This is important for all ex-DMPA-users (whether over 40 or over 50) as, ***if*** they are still fertile, ovulation might resume after a prolonged delay.

POPs, or implant (IMP), or LNG-IUSs: these, though also menses-hiding contraceptives, cause negligible medical risks well into the 50s. So it is entirely acceptable to follow the next plan:

<> **Plan B. Switch to or continue with one of the latter, *progestogen-only contraceptives* and then just stop when the latest age of potential fertility is reached.**

When is that latest fertile age? A good guess is age 55, because, as the FSRH Guideline[45] states:

"…spontaneous conception after this age is exceptionally uncommon even in women still experiencing some menstrual bleeding" - and a large majority will anyway continue amenorrhoeic after stopping hormonal FP. However a small minority of c 4 % (a figure based on work in the 1960s, so maybe a few % more with greater average health these days) may menstruate apparently normally beyond 55. Hence after ceasing** the masking hormonal method, JG advises use for 8 weeks of a simple method. Gygel spermicide via applicator should suffice, due to minimal residual fertility at this age (JG), and generally can cease after the 8 weeks. Those *very* few women who have bleeds in that time (or, as they must be instructed, report any bleeds later) are advised:
<> to continue with spermicide or barrier contraception and report back when their periods *finally* seem to have ceased.
OR:
<> to go back on POP/IMP which are safe almost to any age

NB: FSH testing is usually unhelpful, for diagnosis of loss of ovarian function**!** Hence, *neither* of the above plans propose using FSH for any guidance re final ovarian failure.

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** NB, despite possible pressure to leave it alone, it indeed preferable to remove an LNG- IUS, (like all IUDs) after this age: if left *in situ* post-menopausally there are case reports of severe infections including actinomycosis later.

<>Plan C JG's protocol[1,2], for continuing users of a hormonal method who have reached age 50-plus and want to learn sooner than by Plan B if they may - or contrariwise *should not* - stop contraception, is now superseded for most women by the much simpler Plan C in **Table 2 below.**
JG's Protocol/Plan C[2] - on page 352 of Reference **2 -** may still be of interest to a few women who do not wish to continue their IMP/POP/IUS for the one further year advised in Table 2. Provided they have classical vasomotor symptoms and **two** high FSH values 6 weeks apart, along with (as usual) due warnings of lack of 100% certainty, this protocol[2] allows some women to cease FP right then, age 50-1: though they should understand that to go on to follow the one-year rule of Plan A would be "even safer". They should also, *IF any later bleeds occur*, undertake to return to good FP & take advice.
Note: Above age 51, any 'medical' method is usually best quick-started, see Box p 4. Annual risk of conceiving then is < 2/100 women - higher if there are still regular cycles.

Table 2 Recommendations re stopping contraception
[Table 8 of FSRH Guideline 2017[45], with some JG edits]

Contraceptive method	Age 40–50 years	Age >50 years
Non-hormonal (Barrier or IUD)	Stop FP after 2 years of amenorrhoea	**Plan A:** Stop FP after 1 year of amenorrhoea
CHC	Can be continued [IF zero risk factors]	Stop at age 50 with no testing & switch to a non-hormonal method or IMP/POP/LNG-IUS, then follow appropriate advice: ie Plan B or C⬇
DMPA im or sc	Can be continued (WHO 2). But **stop** if FSH is ≥ 30 IU/L, pre-next dose	Stop by age 50 with no test & switch to a non-hormonal method or IMP/POP/LNG-IUS, then follow appropriate advice: Plan B or C⬇
(IMP (POP (LNG-IUS IF a woman wishes to stop any of these FP methods over 50 but *before* age 55, consider **Plan C:**	Can be continued to age 50 and beyond	**Plan B** Stop at age 55 when natural loss of fertility can be assumed for most women**. **Plan C** FSH level can be checked while on method: If FSH level is >30 IU/L, after 1 final year the woman may discontinue her hormonal FP; but must report IF against expectation, she has any later bleed. *However:* If FSH level is ≤ 30 IU/L the method should be continued and FSH level checked again in 1 year.

** See earlier JG text p 12 re ideally having, before giving the "all clear", an assessment time of c 8 weeks using a simple FP method.

Finally, for:
A GLIMPSE INTO THE FUTURE OF FP:
Visit the websites:
www.ncbi.nlm.nih.gov/pmc/articles/PMC2276786
www.ncbi.nlm.nih.gov/pmc/articles/PMC1070882
www.fpa.org.uk/factsheets/contraception-past-present-future

21 messages which may change your practice
(or maybe not, if you were already up to speed!)
[Listed as herein, ie **not** in any specified order of importance]

- COC-taking with pill-free intervals *absent* or *short*, ≤ 4 days, to become the NORM - pp 1-3
- If COC is WHO 3 on the WHO/UKMEC Medical Eligibility Criteria: consider Zoely or Qlaira since they contain natural estradiol - p 3
- NuvaRing = good option for BTB with COCs - p 4
- Quick-starting to be NORM now *esp.* after hormonal EC - but NOT with anti-androgen progests or IUS - p 3
- BUT, post UPA, wait 5 days and only then start progestogens with/without EE - pp 5-6
- The 'Proving not Pregnant Protocol' with Bridging: helps when there is no LMP, but good also to avoid the often *logistic nightmare* of attempting fittings only pre-D7 - p 5
- Cu IUDs are the most effective EC (failure rate 1:1000), till D5 post-ovulation, despite multiple UPSI. Moreover FP continues till and maybe well beyond the NMP- p 5,6
- Pain relief for Nexplanon insertion – use *minimum* LA or option of ethyl chloride spray [Cryogesic®] - p 7
- NET 1 mg (1000 µg) metabolises to give 4 µg of EE, therefore 5 mg tds to treat bleeding symptoms or postpone periods equates to a high-dose COC - p 7
- Sayana Press is DMPA sc and close to same cost as Depo-Provera, and moreover is self-injectable, aided by a web-based animated film - pp 7-8
- IUDs and IUSs are arguably the *best of the best* among FP methods - pp 8-10
- IUSs as alternative to Nexplanon, if bleeding pattern is unacceptable - p 7, 9
- FP post-surgical abortions to be an IUD or IUS: this to be a new NORM when counselling - p 9
- Pain relief for IUC insertions by naproxen or mefenamic acid + the value of 10% lidocaine spray to the surface and into cervix - p 10
- No routine f'ups: "Open house" policy is best for most methods - p 8, 10
- Vasectomy should, routinely, be done by the "No scalpel" technique - p 10
- Eloine first choice now for acne, ***not*** Yasmin. Dianette (or one of its clones) = 2nd choice when necessary - p 11
- Migraine aura, how to diagnose by *hand-waved-by-head* when patient describes it - p 11!
- Ethinylestradiol in COCs may cause lamotrigine to fail (hence seizure risk) - p 11-12
- For ?ovarian failure at menopause: see Table 2, p13
- 'D' Check-list for unwanted bleeding, with any FP - p 14

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[Comments re this document are invited, via email as above]

APPENDIX

WHO Medical Eligibility Criteria.	[**UKMEC** 1 to 4 is UK adaptation: http://mag.digitalpc.co.uk/fvx/fsrh/ukmec/2016]
CATEGORY [with JG's ABCD added**]**	**BECAUSE:**
WHO 1 - or A for *Always* usable	**No associated risks**
WHO 2 - or B for *Broadly* usable	**Benefits > risks**
**********	**********
WHO 3 - or C for *Caution/Counsel**	**Risks usually > benefits** * Starting point for the '**C**ounsel' is: "it would be better not to use this method" ie say it is not recommended *unless* other more appropriate methods are not available or not acceptable, and taking account of woman's risks in pregnancy
WHO 4 - or D for *Do not use*	**Risks >>> benefits,** an unacceptable health risk

The D-checklist for abnormal bleeding in a 21/7 COC-user: from Contraception Today 7th Ed (2016) p. 59

- **DISEASE**: Consider examining the cervix. Is the BTB due to *Chlamydia* or a polyp (or cancer?)
- **DISORDERS of PREGNANCY** that cause bleeding. Retained products if COC was started after a recent termination of pregnancy? Or, could it be early in gestation of an ectopic pregnancy?
- **DEFAULT**: BTB 2 or 3 days *after* missed Pills episode and persistent thereafter.
- **DRUGS,** if they are enzyme inducers (see text). Cigarettes are also "drugs": BTB is more common among smokers.
- **Diarrhoea and/or VOMITING:** Diarrhoea alone has to be "cholera-like" to impair absorption.
- **DISTURBANCES of ABSORPTION:** For example, after massive gut resection (rare).
- **DURATION of USE** too short: BTB after starting on any new formulation may settle, if the 21/7 pill taker perseveres for 3 months. However during tricycling or 365/365 sustained use, the duration of continuous use may be such that that woman's endometrium is unstable, in which case a 4-day bleeding-triggered break may be usefully taken (see text).
- **DOSE**: After the foregoing have been excluded, it is possible to try

– A phasic Pill if the woman is receiving monophasic treatment.

– Increasing the dose, usually of the progestogen. OR: – A different progestogen OR:

– **NuvaRing**® might be tried, which in RCT produced less BTB/spotting in the first year than Microgynon 30.

Usefully, this check-list is also applicable to the methods other than the COC, with obvious adaptations (eg bullets 3,5 & 6 being not relevant to the vaginal, parenteral or intrauterine methods).

Acknowledgement: adapted from Sapire E. *Contraception and Sexuality in Health and Disease.* New York: McGraw-Hill, 1990.

GLOSSARY

AF atrial fibrillation / **BMI** body mass index / **BTB** breakthrough bleeding+spotting / **CHC** combined *hormonal* contraceptive(s) / **C-Is** contraindications / **COC** combined *oral* contraceptive(s) / **CPA** cyproterone acetate / **Cx** cervix / **DM** diabetes mellitus / **DMPA** depot medroxyprogesterone acetate, either as Sayana Press or Depo-Provera / **DSG** desogestrel / **DSP** drospirenone / **E2** estradiol / **EC** emergency contraception / **EE** ethinylestradiol / **EID** (liver) enzyme-inducing drug / **EMA** European Medicines Agency / **FP** family planning (method) / **fpa** Family Planning Association / **FSH** follicle-stimulating hormone / **FSRH** Faculty, of Sexual and Reproductive Health / **GSD** gestodene / **IU** international unit(s) / **IUC (IUD)(IUS)** / intrauterine contraceptive (device) (system) / **im** intramuscular / **IMP** implant (Nexplanon in UK) / **LA(GA)** local (general) anaesthesia / **LAM** lactational amenorrhoea *method* / **LARCs** long-acting reversible contraceptives / **LMP-NMP** last-*next* menstrual period / **LNG** levonorgestrel / **NET** norethisterone / **NICE** National Institute of Clinical Excellence / **NSAID** non-steroidal anti-inflammatory drug / **PFI** pill-free interval / **PGD** patient group direction/ **PIL** patient information leaflet / **PK** pharmacokinetic/ **PMB** perimenopausal bleeding / **PMS** premenstrual syndrome / **POP** progestogen-only pill / **RCOG** Royal College of Obstetricians & Gynaecologists / **RCT** randomised controlled trial / **sc** subcutaneous / **SDI** subdermal implant / **SPC** Summary of Product Characteristics / **STI** sexually transmitted infection(s) / **UKMEC** UK Medical Eligibility Criteria / **UPA** ulipristal acetate / **UPSI** unprotected sexual intercourse / **UULP** unlicensed use of a licensed product: where used unqualified, here, **UULP** means ***"follow the good practice in the box on p.1"***] / **U/S** ultrasound / **VTE** venous thrombo-embolism / **WHO** World Health Organisation.

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SOME 'BELIEVABLE' WEBSITES IN SRH

- www.margaretpyke.org
  London local services, FP research, and Training Courses on offer
- www.who.int/reproductive-health
  Access to WHO's invaluable e-publications including latest Eligibility criteria & Practice recommendations, also the Global Handbook on FP
- www.rcog.org.uk
  Evidence-based College Guidelines on infertility and menorrhagia
- www.fsrh.org
- Website of FSRH, includes numerous Faculty Guidance pdfs re FP, male & female sterilization, access to the Journal, UK MEC Tables and more
- www.nice.org.uk
  Particularly useful for its LARC & Menopause Guidelines
- www.fpa.org.uk
  Patient information &essential leaflets!
- www.brook.org.uk
  Similar to fpa website but for < 25s; plus a secure on-line enquiry service. Helpline 0800 0185023
- www.fertilityuk.org*The best* URL re fertility awareness methods, for clinicians & for couples.
- www.bashh.org
  National guidelines for all STIs & listing of GUM Clinics in the UK
- www.gmc-uk.org/guidance/ethical_guidance/children_guidance_index.asp
  Ethical guidance for all doctors, on all that relates to the age-group 0-18
- www.likeitis.org.uk ; www.sexunzipped.co.uk
  www.nhs.uk/Livewell/Sexandyoungpeople
  www.scarleteen.com
  All these are user-friendly, accurate, and empowering for young people accessing SRH – whether for FP or STIs
- www.familylives.org.uk [formerly parentline plus]
  Top tips for parents, to help teens/pre-teens avoid many kinds of grief
- www.ecotimecapsule.com[1] & www.populationmatters.org[2]
  [[1]This describes JG's 'Apology to the Future' project and contains his TED lecture *"Sex & the Planet"* & ***"The Promise"*** video.
  [2] This contains the pdf entitled Y*outhquake*]

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  mail order for options in modern oil-resistant plastic condoms.

JG, October 2017