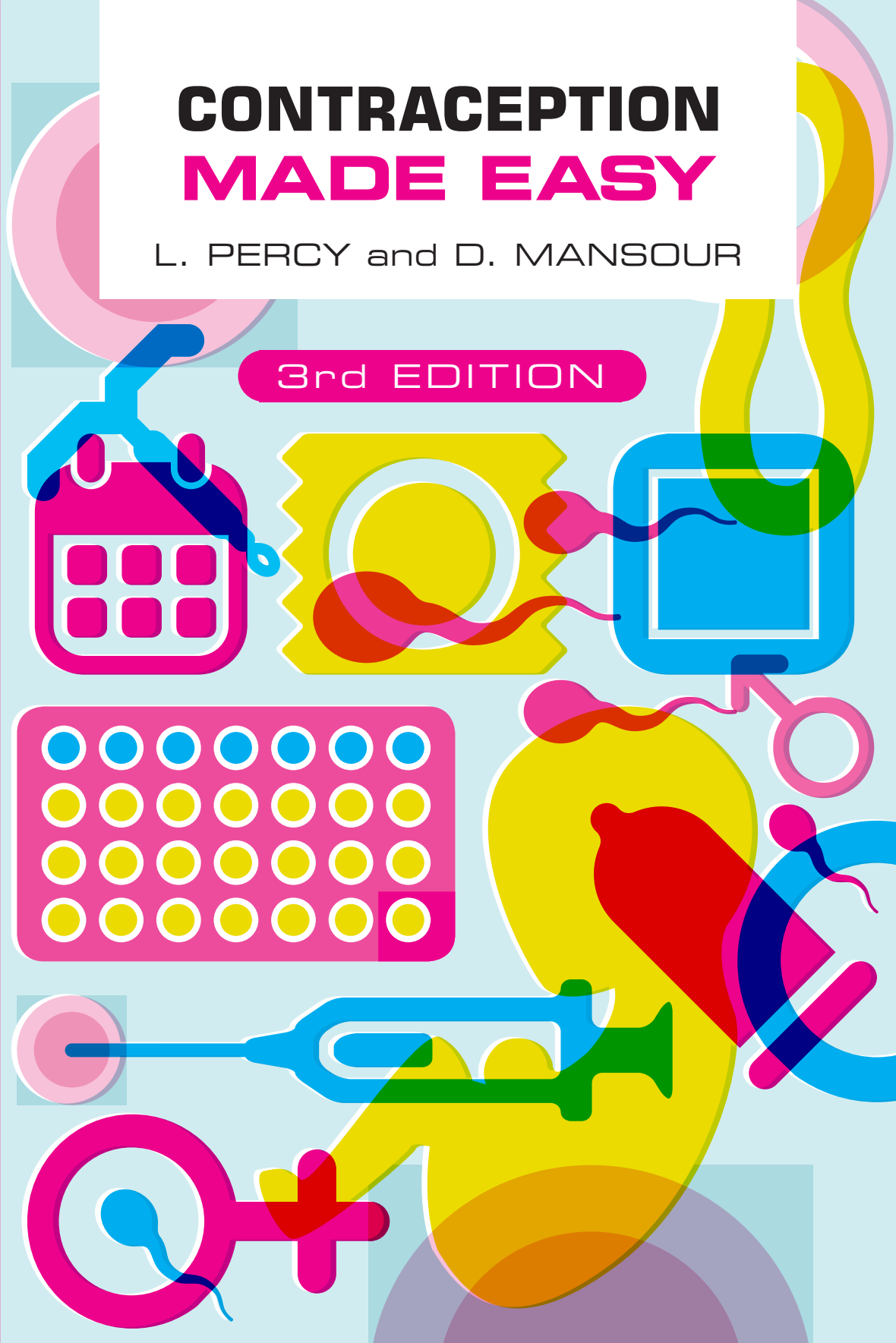
CONTRACEPTION MADE EASY

L. PERCY and D. MANSOUR

3rd EDITION



CONTRACEPTION
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CONTRACEPTION MADE EASY

THIRD EDITION

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Chapter 5

Progestogen-only pill

The progestogen-only pill (POP) is taken by about 6% of women aged 16–49 years in the UK, although it is less popular in other European countries. Almost half of the prescriptions in 2020 for oral contraception were for a POP. A desogestrel POP is now available to buy from pharmacies.

5.1 Potential users

5.1.1 Most appropriate users

Almost all women who require contraception can take a POP.

5.1.2 Not suitable for the following users

The POP may not be effective in women taking liver enzyme inducing drugs and should be avoided in women who:

- have had a hormone-dependent tumour (e.g. breast cancer) in the last 5 years
- have severe decompensating cirrhosis or liver tumours
- are sensitive to any of the components of the POP
- are currently taking a POP and develop ischaemic heart or cerebrovascular disease.

Generic desogestrel POPs contain soybean oil and are contraindicated in those with a peanut allergy. Branded tablets such as Cerazette, Cerelle and Zelleta should be prescribed by name, as they do not contain this oil. All oral COCs and POPs contain lactose as an excipient in a small dose and should not affect most women unless they have severe lactose intolerance.

5.2 Available POPs in the UK

These are listed in *Table 5.1*.

Table 5.1 POPs currently available in the UK

Trade name	Progestogen and dose	Price (NHS indicative price)
Noriday	Norethisterone 350 micrograms	84 tablets Drug tariff £2.10 (£2.10)
Norgeston	Levonorgestrel 30 micrograms	35 tablets Drug tariff £0.92 (£0.92)
Cerazette Cerelle Desogestrel generic Dosomono Desorex Feanolla Zelleta	Desogestrel 75 micrograms	84 tablets Drug tariff £2.36 (£9.55) 84 tablets Drug tariff £2.36 (£4.30) 84 tablets Drug tariff £2.36 (varies) 84 tablets Drug tariff £2.36 (£6.50) 84 tablets Drug tariff £2.36 (£2.45) 84 tablets Drug tariff £2.36 (£3.49) 84 tablets Drug tariff £2.36 (£2.98)

Data from *BNF*, 2023.

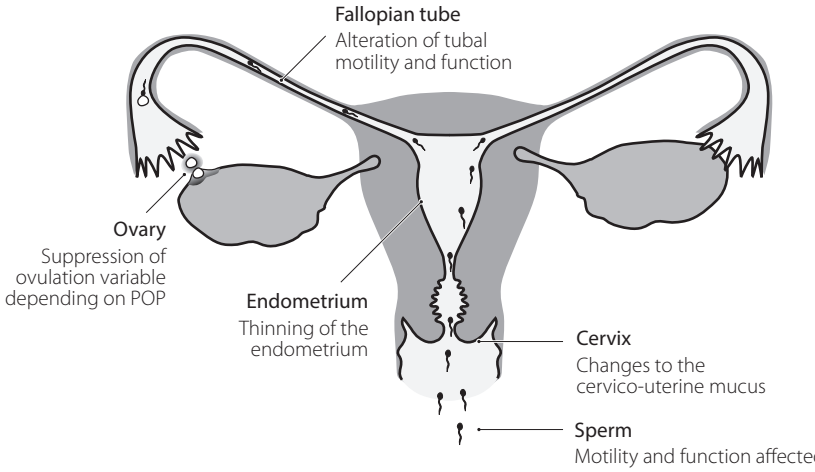

Figure 5.1 Mechanism of action for POPs.

5.3 Mechanism of action

The mechanisms of action are illustrated in *Figure 5.1*.

- Ovulation may be suppressed in up to 60% of cycles by POPs containing levonorgestrel or norethisterone, but in up to 97–99% by those containing desogestrel.
- All POPs alter the cervical mucus to reduce sperm penetration into the upper genital tract.
- POPs induce changes in the endometrium to prevent sperm survival and implantation of the blastocyst.
- Sperm motility and function is affected, preventing fertilization.

5.4 Efficacy of POPs

The POP is very effective when taken consistently and correctly; with 'perfect use' the failure rate is less than 1%. However, the typical failure rate is 7% in the first year of use (see *Table 1.1*). The desogestrel POP is first line for most women as it is thought to be more effective than traditional POPs (as it usually inhibits ovulation and has a 12 rather than 3 hour safety window), but this has not been shown in any published study.

5.5 Pros and cons of POPs

5.5.1 Advantages

- Unrelated to sexual intercourse.
- Simple, convenient to use, and under the woman's control.
- Can be taken when breastfeeding.
- May help to reduce dysmenorrhoea and also the severity of migraines.
- Ideal for women who suffer from oestrogenic side-effects when using CHC, e.g. breast tenderness, headaches including migraines, fluid retention, leg cramps or nausea.

- Suitable for women over 35 years who smoke.
- Can be used in overweight or obese women with no dose adjustment.
- Can be taken by those with medical illnesses where CHCs are contraindicated, e.g. women with hypertension, migraine with focal aura, or with a previous personal history of VTE.
- No evidence of an increased risk of cardiovascular disease, thromboembolism or stroke.
- Minimal alteration in carbohydrate and lipid metabolism, therefore a useful option for diabetics, even those with neuropathic or nephropathic complications.

5.5.2 Disadvantages

- Some women complain of nuisance side-effects such as breast tenderness, mood changes, headaches or acne.
- Overall risk of pregnancy is reduced when taking a POP, but 1 in 10 of these pregnancies may be ectopic in traditional POP users.
- Can alter ovulation, thereby disrupting the menstrual bleeding pattern, with users reporting increased breakthrough bleeding, spotting and amenorrhoea.
- Functional ovarian cysts may develop in a small number of women; however, these tend to be transient and rarely require surgical intervention.

5.6 Using the POP

The POP is taken every day with no break. Following oral ingestion the effect on the cervical mucus reaches its peak within 2–3 hours then slowly wanes over the next 22 or so hours. POPs containing desogestrel differ from more traditional POPs because the main mode of action is to inhibit ovulation and so these POPs have a 12 hour rather than a 3 hour safety window. Women who normally take their traditional POP at 8 am have up to 11 am that day to take their pill. Those taking a desogestrel POP have until 8 pm that night (see advice on missed pills in *Section 5.6.2*).

The efficacy of the POP may be affected by vomiting or severe diarrhoea:

- If vomiting occurs within 2 hours of taking the POP, another pill is taken and no further action is required.
- If vomiting continues and/or an individual is 3 or more hours later than normal taking the pill (12 hours for a desogestrel POP), then the missed pill guidance should be followed.

The efficacy of the POP can be affected by concomitant use of a liver enzyme inducing drug, such as carbamazepine, phenobarbital, phenytoin, topiramate, rifabutin, rifampicin, some antiretrovirals, ulipristal acetate, bosentan, St John's wort and possibly lamotrigine.

- When these drugs are used short term, an additional method such as condoms should be used during the time of drug administration and for 4 weeks after stopping the medication.
- An alternative method such as an injectable or intrauterine contraceptive should be chosen if the liver enzyme inducing drug is to be used long term.

5.6.1 Starting regimens

These are described in *Table 5.2* below.

Table 5.2 Starting regimens for POPs

Circumstances	Start when?	Requirement for 2 days (48 hours) of additional contraceptive precautions?
Natural menstrual cycle	Up to and including day 5 At any other time if it is reasonably certain she is not pregnant and/or a high sensitivity urine pregnancy test (HSUPT) is negative	No Yes
Amenorrhoea	At any time if it is reasonably certain she is not pregnant and/or HSUPT is negative	Yes
Quick starting	At any time if it is reasonably certain she is not pregnant or a HSUPT is negative (see *Chapter 2*)	Yes
Following childbirth (breastfeeding and non-breastfeeding)	Up to day 21 post-partum After day 21 post-partum	No Yes (unless using LAM)
Following abortion, miscarriage, ectopic pregnancy or gestational trophoblastic disease	Day 1–5 After day 5 if it is reasonably certain she is not pregnant	No Yes
Following oral emergency contraception		
• after LNG-EC	Immediately	Yes
• after UPA- EC	No sooner than 5 days after taking UPA-EC	Yes
Switching from another POP	At any time	No
Switching from a CHC	Day 1–2 of HFI Day 3–7 of HFI or week 1 following Week 2–3 of CHC	No Yes If UPSI has occurred after day 3 of HFI advise continuing CHC for 7 days No, providing the method has been used consistently and correctly prior to switching
Switching from progestogen-only anovulatory methods		
• injectable	Start any time up to when repeat injection is due	No
• implant	Start any time up to when implant is due for removal	No

(continued)

Circumstances	Start when?	Requirement for 2 days (48 hours) of additional contraceptive precautions?
Switching from LNG-IUS	Start at any time	Yes if IUS removed on day of method changed, or No if LNG-IUS remains *in situ* for 2 days until the POP becomes effective If there has been any UPSI in the preceding 7 days the LNG-IUS should be left *in situ* for 7 days
Switching from IUD	Day 1–5 of cycle After day 5 of cycle	No Yes if IUD removed on day of method changed, or No if IUD remains *in situ* for 2 days until the POP becomes effective If there has been any UPSI in the preceding 7 days the IUD should be left *in situ* for 7 days

5.6.2 Advice about missed pills

- POPs are effective if taken consistently and correctly.
- If less than 3 hours has elapsed from the usual administration/ingestion time for a norethisterone or levonorgestrel-containing POP and less than 12 hours for a desogestrel-containing pill, the missed pill should be taken and the pack continued as normal. No additional cover (e.g. condoms) is required.
- If more than 3 hours has elapsed from the normal administration time (12 hours for desogestrel POP) then the last missed pill is taken, the pack continued as normal, but condoms should also be used as additional contraception for the next 48 hours.
- If more than 3 hours has elapsed from the normal administration time (12 hours for desogestrel POP) and unprotected sex has occurred, emergency contraception should be considered (see *Chapter 13*).

5.7 Routine follow-up

Women can be prescribed or provided with up to a 12-month supply of POP if there are no concerns. Earlier review may be required if nuisance side-effects or compliance concerns are present. POPs can be continued until the age of 55 when 98% of women are at least 1 year after their last natural period. For additional information see *Chapter 3*.

5.8 Return to fertility

There is no delay in return to fertility. Most women ovulate within 2–3 weeks of discontinuing POPs.

5.9 Managing side-effects

Non-specific symptoms such as headache, fatigue and mood change are common in the general population. Treatment-associated serious adverse reactions are very rare with POPs but an irregular bleeding pattern is common and some patients report possible progestogen-associated side-effects.

- In women taking traditional POPs bleeding is unpredictable: 20% will have no periods, 40% irregular bleeding and 40% will have regular cycles. Those taking desogestrel rather than traditional POPs are more likely to have no or infrequent periods after 1 year of use.
- Encourage women to continue with the method for at least 3 months. In those with persistent troublesome bleeding, check compliance and drug interactions, exclude any STIs and pregnancy, examine the cervix and perform cervical cytology if due. Consider a change in POP or contraceptive method.
- Progestogen-associated side-effects may include acne, bloating, mood change and loss of libido. Again, encourage women to continue with the method for at least 3 months. If symptoms persist consider changing the POP to a different progestogen or consider a different method.
- There is no evidence that POPs increase or decrease weight.

5.10 Myths and misconceptions

- **POPs are not very effective in women weighing over 70 kg and these women need to take 2 POPs daily** – there is no evidence that POPs are less effective in overweight or obese women and so standard dosing regimens should be followed.
- **Women taking POPs and having amenorrhoea will have problems getting pregnant** – some women will not bleed while taking a POP. The endometrium is thin and atrophic. This is seen as an additional benefit, with many reporting reduced period pain too. On discontinuation of the POP most women ovulate within the first 3 weeks and menstruate within the next 6 weeks. The POP has no long-term effect on fertility.
- **Women with migraine with aura cannot take POPs** – this is not true. In fact many women with migraine with aura choose to take a POP for contraception because it may help reduce the intensity and frequency of the headaches and aura.

EXAMPLE

An 18 year old woman presents with painful, heavy periods; she also needs contraception. She would like to take the COC. History-taking establishes that her father experienced an unprovoked VTE at the age of 38 years, but there is no other family history of VTE. The family were genetically screened because her father was found to have factor V Leiden; only her sister was found to carry the gene for factor V Leiden.

What do you advise?

1. Using UKMEC this family history suggests that the risks of taking a COC outweigh any potential benefits (UKMEC 3), even though her thrombophilia screen was normal. This is because we can only look for known mutations and she may carry an increased VTE risk from an unknown alteration in genetic sequencing. This should be explained to the patient.
2. Alternatives with a lower risk for this woman would be a desogestrel POP, etonogestrel implant, DMPA or a LNG-IUS.

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