



Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit

A unit funded by the FSRH and supported by NHS Greater Glasgow & Clyde to provide guidance on evidence-based practice

CEU Statement (May 2011) Missed Pill Recommendations

(To be reviewed by May 2012)

Background

In 2005, the Faculty of Sexual and Reproductive Healthcare (FSRH) updated the original guidance on missed combined oral contraceptive pills (COCs)¹ following publication of revised evidence-based recommendations from the World Health Organization.² Advice in the new rules varied depending on the strength of the pill ($\geq 30 \mu\text{g}$ or $< 30 \mu\text{g}$ ethinylestradiol). The scientific evidence base has not changed significantly since 2005, however anecdotal evidence suggests that women and health professionals find the current rules complicated and difficult to use. The rules have not been universally adopted and the pharmaceutical companies that manufacture COCs have continued to advise the original missed pill rules in patient information leaflets.

As a result the UK Medicines and Healthcare products Regulatory Agency (MHRA) identified a need for clearer, more consistent missed pill rules. In 2010, the MHRA asked the FSRH Clinical Effectiveness Unit (CEU) to review its advice on missed pills with the aim of agreeing new harmonised recommendations based on advice from the Commission on Human Medicines (CHM). New advice has been approved by the FSRH and the Family Planning Association (FPA). Future FSRH guidance documents and FPA literature will include these revised rules, which apply to all COCs with an estrogen dose of at least $20 \mu\text{g}$ (with the exception of the estradiol valerate-containing pill, Qlaira[®]), whether monophasic or phasic and including every day (ED) preparations. The MHRA has asked pharmaceutical companies marketing COCs to amend their patient information leaflets in line with CHM advice. The CEU will be producing guidance on combined hormonal contraception in 2011 that will also include advice on how to deal with incorrect use of the combined patch and combined vaginal ring.

Key elements of revised advice

- If it is reasonably certain that the woman is not pregnant, COCs can be initiated on any day of the menstrual cycle, not just the first day. Additional contraceptive precautions are required for the first 7 days if the pills are started after Day 5 of the cycle.
- If one active pill is missed, there is no need to take additional precautions.
- If two active pills are missed, additional precautions should be taken for the next 7 days.

The full wording of the revised advice is reproduced on page 2, together with further explanation contained within a flow chart produced by the CEU (page 3). Advice on use of Qlaira[®], Evra[®] and NuvaRing[®] can be found in the Summaries of Product Characteristics and patient information leaflets available at <http://www.medicines.org.uk/emc>.

CEU explanatory notes

Definition of a missed pill

A missed pill is defined as one that is more than 24 hours late. If more than one pill is missed, the rule applies to consecutive pills. The rule applies to active pills, not to placebo pills in ED preparations. Further guidance for professionals on how to advise women is given in the flow chart on page 3 produced by the CEU.

Qlaira[®]

This formulation is a quadriphasic pill containing the estrogen estradiol valerate instead of ethinylestradiol. In view of the limited clinical experience with this product to date, it is suggested that the pharmaceutical company's advice should be followed for the time being.

Combined Oral Contraceptive (COC) Pill Advice 2011³

Starting the pill

You can start the pill any time in your menstrual cycle if you are sure you are not pregnant.

If you start the pill on the first day of your period you will be protected from pregnancy immediately.

You can also start the pill up to, and including, the fifth day of your period and you will be protected from pregnancy immediately.

If you start the pill at any other time in your menstrual cycle you will need to use additional contraception, such as condoms, for the first 7 days of pill taking.

If you forget to take a pill or start a pack late

Missing pills or starting the pack late may make your pill less effective. The chance of pregnancy after missing pills depends on **when** pills are missed and **how many** pills are missed. A pill is late when you have forgotten to take it at the usual time. A pill has been missed when it is more than 24 hours since the time you should have taken it.

If you miss one pill anywhere in your pack or start the new pack 1 day late, you will still have contraceptive cover. However, missing **two or more pills** or starting the pack **two or more days late** (more than 48 hours late) may affect your contraceptive cover. As soon as you realise you have missed any pills, take the last pill you missed immediately. In particular, during the 7-day pill-free break your ovaries are not getting any effects from the pill. If you make this pill-free break longer by forgetting two or more pills, your ovaries might release an egg and there is a real risk of becoming pregnant.

Follow the advice below. If you are not sure what to do, continue to take your pill and use additional contraception, such as condoms, and seek advice as soon as possible.

If you have missed **one pill**, anywhere in the pack:

- Take the last pill you missed now even if it means taking two pills in one day
- Continue taking the rest of the pack as usual
- No additional contraception needed
- Take your 7-day break as normal.

If you have missed **two or more pills (i.e. more than 48 hours late)**, anywhere in the pack:

- Take the last pill you missed now even if it means taking two pills in one day
- Leave any earlier missed pills
- Continue taking the rest of the pack as usual and use an extra method of contraception for the next 7 days
- You may need emergency contraception (see below)
- You may need to start the next pack of pills without a break (see below).

Emergency contraception

If you have had unprotected sex in the previous 7 days and you have missed two or more pills (i.e. more than 48 hours late) **in the first week of a pack**, you may need emergency contraception. Get advice from your contraception clinic, family doctor or a pharmacist about this.

Starting the next pack after missing two or more pills (more than 48 hours late)

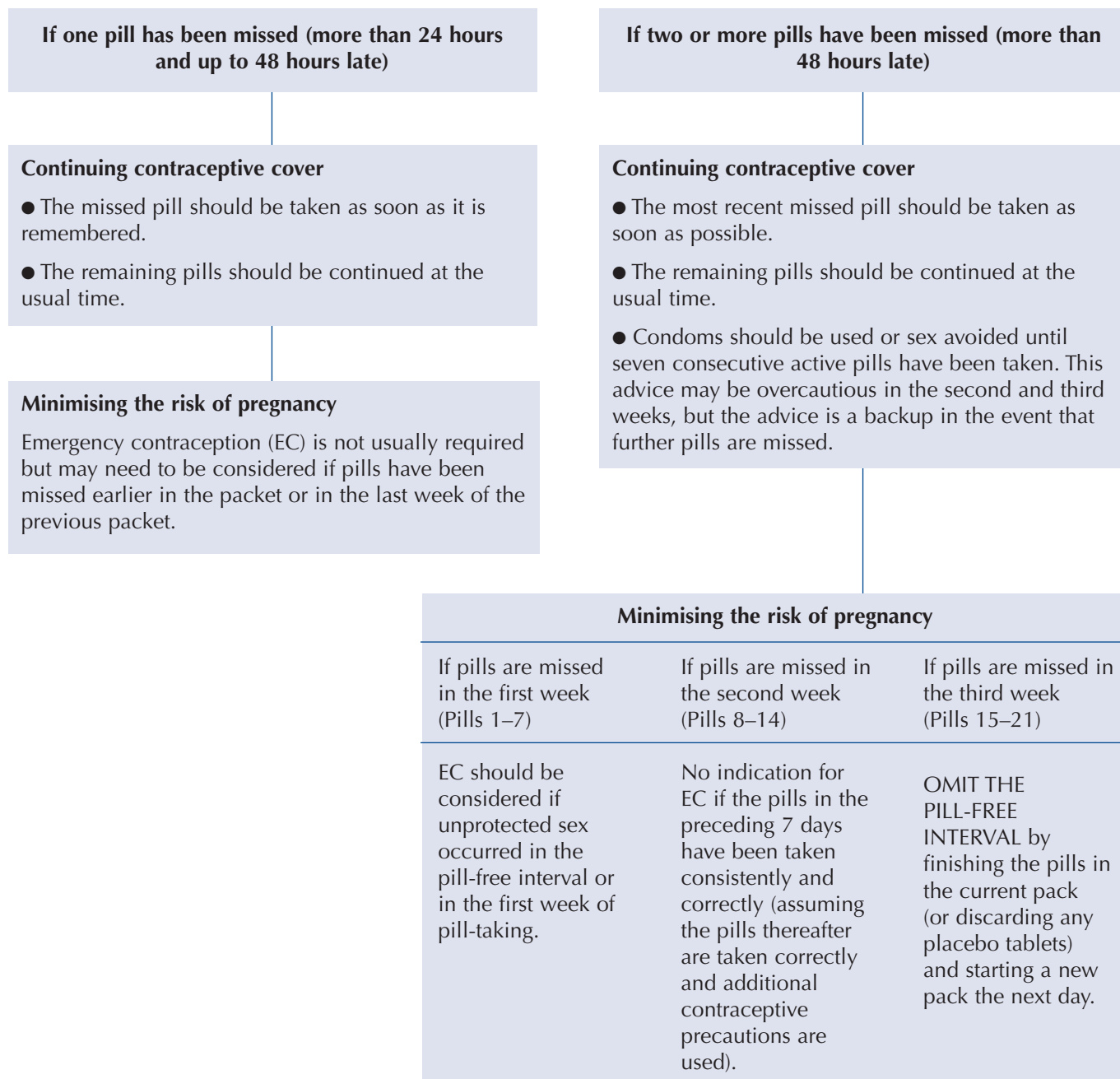
If **seven or more** pills are left in the pack after the last missed pill:

- Finish the pack
- Have the usual 7-day break.

If **less than seven** pills are left in the pack after the missed pill:

- Finish the pack and begin a new one the next day (this means missing out the break).

MISSED COMBINED ORAL CONTRACEPTIVE PILLS (COCs): CEU ADVICE FOR HEALTH PROFESSIONALS



References

- 1 Faculty of Family Planning and Reproductive Health Care. Missed pills: new recommendations. *J Fam Plann Reprod Health Care* 2005; **31**: 153–156.
- 2 World Health Organization. *Selected Practice Recommendations for Contraceptive Use* (2nd edn). 2004. <http://whqlibdoc.who.int/publications/2004/9241562846.pdf> [Accessed 24 November 2010].
- 3 Medicines and Healthcare products Regulatory Agency (MHRA). *Combined Oral Contraceptives (The Pill): When to Start Taking the Pill, and Missed Pill Advice*. MHRA UK Public Assessment Report, May 2011. <http://www.mhra.gov.uk> [Accessed 12 May 2011].