Appendix 1. Tailored regimens for CHC usage (off licence)

Table 1 Tailored regimens for use of combined hormonal contraception (CHC)		
Type of regimen	**Suggested regimen**	**CHC-free period**
Extended use	Tricycling (3 cycles taken continuously back to back, i.e. 3 pill packets or 3 rings, or 9 patches)	7 days taken after finishing the 3rd packet, 3rd ring or 9th patch
Shortened pill-free interval	3 weeks of CHC use	4 days taken after each packet of pills, each ring or 3rd patch
Extended use with shortened pill-free interval	Method used continuously (≥21 days; pill, patch and ring-free weeks omitted) until breakthrough bleeding occurs for 3–4 days	4-day interval
Extended use with regular pill-free interval	Method used continuously (≥21days; pill, patch and ring-free weeks omitted) until breakthrough bleeding occurs for 3–4 days	7-day interval

Separate guidance on missed pills when using such regimens (and when emergency contraception would be required) is not available. This would be a matter of clinical judgement, based on the missed pill rules for cyclical regimens.

[Headache in the pill-free week is a problem commonly encountered in practice, that can be managed by tailored regimes, in particular tricycling regimes. The reaction by practitioners is often to stop the method and try something else, rather than the simpler answer of tailoring the regime].

Appendix 1 (continued) : UKMEC category definitions

- UKMEC 1 = a medical condition for which there is no restriction for the use of the contraceptive method.

- UKMEC 2 = a medical condition where the advantages of using the method generally outweigh the theoretical or proven risks.

- UKMEC 3 = a medical condition where the theoretical or proven risks usually outweigh the advantages of using the method.

Provision of a contraceptive method, with a medical condition in this category, requires expert clinical judgement and/or referral to a specialist contraceptive provider. This is because the use of the method is not usually recommended, unless other more appropriate methods are not available, or not acceptable.

- UKMEC 4 = a medical condition which represents an unacceptable health risk if the contraceptive method is used.

As these definitions are wordy, it has been decided to use the abbreviations (UKMEC 1, etc) throughout this module.

Applying the UKMEC categories to individual conditions, the table below demonstrates the risk of important medical conditions, which require discussion with all CHC users.

Table 2: Important medical conditions and their UKMEC scores

	Condition	**UKMEC CATEGORY**
VTE	1st degree relative with **VTE** <45	UKMEC 3
	Known **thrombogenic mutation**	UKMEC 4
SMOKING	**> 35 & smokes** <15 cigarettes/day	UKMEC 3
	> 35 & smokes > 15 cigarettes/day	UKMEC 4
	> 35 and ex-smoker for > 1 year	UKMEC 2
MIGRAINE	**Migraine** with aura	UKMEC 4
BP	**Hypertension** : systolic BP > 160	UKMEC 4
	diastolic BP > 95	UKMEC 4
BMI	**BMI** > 35 kg/m2	UKMEC 3
Breast Cancer	Current **breast cancer**	UKMEC 4
	Personal **genetic mutation** associated with breast cancer	UKMEC 3
	Past history of breast cancer, but no evidence of current breast cancer disease for >5 years	UKMEC 3
	Family history of breast cancer	UKMEC 1

Appendix 2: Starting CHC

Table 3 : Starting combined hormonal contraception		
Circumstance	**When to start**	**Additional contraceptive protection required?**
Women having menstrual cycles	Up to and including Day 5 At any other time if it is reasonably certain she is not pregnant	No Yes (7 days)
Women who are amenorrhoeic	At any time if it is reasonably certain she is not pregnant	Yes (7 days)
Postpartum (not breastfeeding) CHC should not be used in breastfeeding women less than 6 weeks postpartum (UKMEC 4). From 6 weeks to 6 months it is UKMEC 3 if fully breastfeeding, and UKMEC 2 if low-medium breastfeeding. CHC is UKMEC 1 if still breastfeeding 6 months postpartum	Start on Day 21 postpartum if no additional risk factors for VTE After Day 21 postpartum, if menstrual cycles have returned, start CHC as for other women having menstrual cycles After Day 21 postpartum if menstrual cycles have not returned, start as you would for amenorrhoeic women	No No if starting up to Day 5 Yes (7 days) if starting after Day 5 Yes (7 days)
Post first- or second-trimester abortion	Up to and including Day 5 post abortion At any other time if it is reasonably certain she is not pregnant	No Yes (7 days)
Postpartum treatment: It should be noted that in 2010 World Health Organization guidance in relation to postpartum women starting CHC was revised, to advise more restrictive use, particularly if women have additional risk factors for venous thromboembolism. Women should ideally start CHC on the day of, or day after, a first- or second-trimester abortion		

Appendix 2: switching between contraceptive methods

Table 4 Clinical Effectiveness Unit advice on switching to and between combined hormonal contraception

Switching from	Switching to	When to start	Additional contraceptive protection required?	Notes
CHC	Another CHC	Start on day after last active COCP, CTP, or CVR	No	If a 7-day interval is taken the need for additional precautions and emergency contraception should be assessed on an individual basis, taking account of correct use before the hormone-free period
Traditional POPs and LNG-IUS (Mirena)	CHC	Can be started immediately if the previous method was used consistently and correctly	Yes (7 days)	The primary mode of action is not inhibition of ovulation, and therefore additional precautions are required in case ovulation occurs before contraceptive efficacy of CHC has been established. The cervical mucus effect may be maintained but there is no evidence to prove adequate contraceptive protection
Progestogen-only anovulatory methods (implant, injectable and desogestrel-only pill)	CHC	Can be started any time up to when the repeat injection is due, or implant is due for removal, or next day after pill	No	The primary mode of action of these methods is inhibition of ovulation. CHC suppresses ovulation by the time the inhibitory effect of the previous method is lost
Non-hormonal method (other than an IUD)	CHC	As per starting advice	No if starting Day 1–5 Yes (7 days) f amenorrhoeic or starting any time after Day 5	As per starting advice
IUD	CHC	Up to Day 5 of menstrual cycle. IUD can be removed at that time. At any other time during the menstrual cycle, or if amenorrhoeic	No Yes (7 days)	 Additional precautions are required unless CHC was started 7 days prior to IUD removal

IUD = intrauterine device.
LNG-IUS = levonorgestrel-releasing intrauterine system
POP= progestogen-only pill

Appendix 3. Non-contraceptive health effects of CHC use.

Condition	CHC effect, if any
Death	12% reduction in all cause mortality, and no overall increased risk of cancer
VTE	See notes below
Ovarian & endometrial cancer	Risk of dying from, or developing these conditions, is reduced
Breast cancer	See notes below
Cervical cancer	Small increase in risk, related to duration of use, which reverts to normal 10 years after stopping CHC
Colorectal cancer	Reduction in risk with CHC
Dysmennorhoea & heavy menstrual bleeding	Limited evidence that lessens pain and reduces bleeding. However NICE recommend use of CHC for these symptoms
Menopausal symptoms	May improve menopausal symptoms, but stop at age 50
Unscheduled bleeding	20% of users (but see info points 27 and 28)
Mood changes	May cause mood changes but does not cause depression
Weight gain*	No association
Acne	Reduces facial acne lesions
Bone health	No effect
Cardiovascular risks	See notes below

VTE

a) CHC use does increase the risk of VTE. There is continuing debate about the effect that the type of progestogen in a COCP has on VTE risk. The MHRA indicates that LNG-containing pills may be the 'safest' pill choice for women starting or switching contraception.

Given none of the newer generation pills have been shown to be associated with a lower risk of VTE, all other considerations being equal, women should probably be offered an older, low-dose formulation in the first instance.

When prescribed appropriately the benefits of using CHC far outweigh the risks of VTE. However a personal history of VTE represents an unacceptable health risk if CHC is used.

VTE and family history

b) A family history of VTE is a poor indicator of risk for those with underlying coagulation problems. The cause of VTE in a family member may not be hereditary (e.g. it may have occurred during pregnancy or a period of immobilisation) and many women with a family history of VTE never develop a VTE. Having a first-degree relative with a history of VTE under the age of 45 years, is a UKMEC 3.

c) Women with reduced levels of naturally occurring anticoagulants (anti-thrombin III, Protein C or Protein S) or factor V Leiden or prothrombin gene mutations (G20210A) are predisposed to VTE. Indeed women with factor V Leiden mutations can have up to a 35-fold increased risk of thrombosis with COCP use.

d) Having a known thrombogenic mutation represents an unacceptable risk if CHC is used (UKMEC 4).

The general use of thrombophilia screening prior to CHC use is not recommended. A negative screen may not exclude all types of thrombophilia.

Cardiovascular disease and stroke

e) Many studies have investigated associations between COCP use and arterial vascular disease. While some authors have not found an association with myocardial infarction (MI), other papers including two meta-analyses, have shown an increased risk of MI in COCP users, particularly smokers.

For women over the age of 35 years who smoke <15 cigarettes per day, use of CHC is UKMEC 3; for those who smoke >15 cigarettes per day, use is UKMEC 4.

As the risk declines with time after stopping smoking, use of CHC in former smokers aged >35 years changes to UKMEC 2 a year or more after stopping.

f) With regard to cerebrovascular disease, although a meta-analysis reported a two-fold increase in risk of ischaemic stroke with use of low dose COCPs, other studies have not found that COCP use results in a statistically significant increased risk of ischaemic or haemorrhagic stroke.

Migraine

g) The risk of stroke is increased in COCP users with migraine compared to COCP users without migraine. The risk of stroke associated with migraine appears only to affect those individuals experiencing migraine with aura, and that oral contraceptive use further increases the risk of ischaemic stroke.

Use of CHC in the presence of migraine with aura is UKMEC 4.

Hypertension

h) Risk of vascular disease may be influenced by other independent risk factors such as hypertension and obesity. Hypertensive COCP users have been found to be at higher risk of stroke and MI, but not VTE, than hypertensive non-COCP users.

Systolic BP >160 mmHg or diastolic BP >95 mmHg is UKMEC 4. Although there are no data, CHC users whose BP is adequately controlled by treatment may be at lower risk (UKMEC 3).

Obesity

i) As obesity is associated with an increased risk of cardiovascular, cerebrovascular and venous thromboembolic disease, use of CHC needs careful consideration in obese women.

There was published criticism of the 2005 UKMEC categories attributed to the use of CHC in obese women suggesting they were overly restrictive in comparison to other UKMEC categories.

* When UKMEC was revised in 2009 the UKMEC 4 category (which previously applied to BMI >40 kg/m2) was removed, and UKMEC 3 applied to BMI >35 kg/m2 with no absolute restriction on CHC use based on weight alone.

Breast Cancer

j) A large meta-analysis of case-control studies from 25 countries showed an increased risk of breast cancer whilst using COCP which is approximately an increase of 24% above the background risk.

This study suggested that any excess risk of breast cancer associated with COCP use increases quickly after starting, does not increase with duration of use, and disappears within 10 years of stopping COCP use.

Whilst some studies have similarly reported a statistically significant increased risk, others have reported findings of borderline or no statistical significance.

Use of COCPs have not been found to be associated with increased mortality from breast cancer.

Breast cancer and family history

k) For women with a family history of breast cancer, there is an increased risk of breast cancer compared to women with no family history. Although the background risk is increased, current evidence shows that risk of breast cancer amongst women with a family history is not increased further by using COCPs.

A family history of breast cancer therefore does not restrict use of CHC (UKMEC 1).

l) Evidence is conflicting on whether women who are carriers of BRCA1 or BRCA2 mutations are at further increased risk of breast cancer with COCP use. Carriers have a higher baseline risk when compared to the general population and therefore any potential small risk may be significant.

Current guidance states that having a genetic mutation associated with breast cancer is UKMEC 3. It is not known where the balance of risk lies with regard to protection from ovarian cancer and risk of breast cancer in BRCA mutation carriers.

Current breast cancer

m) Current breast cancer is a condition which represents an unacceptable risk if CHC is used (UKMEC 4), while past and no evidence of current disease for 5 years is UKMEC 3.

There is currently a lack of data on which to make separate recommendations with regard to women who have estrogen and/or progesterone receptor-negative disease.

UKMEC does not differentiate between types of breast cancer and therefore the category applies to women with all types. Consult with a woman's oncologist if there is clinical uncertainty.

Ovarian and endometrial cancer

n) Amongst BRCA mutation carriers, COCP use has been shown to provide a protective effect against ovarian cancer. Data also suggest a reduction in the incidence of ovarian cysts and benign ovarian tumours amongst women using COCPs.

Much of the above information is also provided in tabular format in Appendix 1.

APPENDIX 4 - MISSED PILL ADVICE.

If ONE pill has been missed (48–72 hours since last pill in current packet **or 24–48 hours late** starting first pill in new packet)

Continuing contraceptive cover

- The missed pill should be taken as soon as it is remembered.
- The remaining pills should be continued at the usual time.

Minimising the risk of pregnancy

Emergency contraception (EC) is not usually required but may need to be considered if pills have been missed earlier in the packet or in the last week of the previous packet.

If TWO OR MORE pills have been missed (>72 hours since last pill in current packet **or >48 hours late** starting first pill in new packet**)**

Continuing contraceptive cover

- The most recent missed pill should be taken as soon as possible.
- The remaining pills should be continued at the usual time.
- Condoms should be used or sex avoided until seven consecutive active pills have been taken. This advice may be overcautious in the second and third weeks, but the advice is a backup in the event that further pills are missed.

Minimising the risk of pregnancy

If pills are missed in the first week (Pills 1–7)	If pills are missed in the second week (Pills 8–14)	If pills are missed in the third week (Pills 15–21)
EC should be considered if unprotected sex occurred in the pill-free interval or in the first week of pill-taking.	No indication for EC if the pills in the preceding 7 days have been taken consistently and correctly (assuming the pills thereafter are taken correctly and additional contraceptive precautions are used).	OMIT THE PILL-FREE INTERVAL by finishing the pills in the current pack (or discarding any placebo tablets) and starting a new pack the next day.

Advice on the use of the CTP and CVR is given on the next page

Appendix 4 (continued): summary of advice in relation to incorrect use of the combined transdermal patch/combined vaginal ring

Situation	Timeframe	Additional contraceptive measures required?
Extension of patch/ring-free interval	≤48 hours	No
	>48 hours	Yes (7 days). Consider emergency contraception if unprotected sexual intercourse occurred in patch/ring-free interval
Patch/ring detachment/removal	≤48 hours	No (providing there has been consistent and correct use for 7 days prior to removal/detachment)
	>48 hours	Yes (7 days). Consider emergency contraception if patch/ring was detached/removed in Week 1 and unprotected sexual intercourse occurred in patch/ring-free interval or Week 1
Extended use of Patch	≤9 days	No
	>9 days	Yes (7 days)
Extended use of the ring	≤4 weeks	No (ring-free interval can be taken)
	>4 weeks	Yes. However, if the woman has worn the ring for >4 but ≤5 weeks, efficacy could be maintained by starting a new ring immediately without a ring-free interval