FACULTY OF SEXUAL & REPRODUCTIVE HEALTHCARE

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Faculty of Sexual & Reproductive Healthcare Clinical Guidance



Contraceptive Choices for Women with Cardiac Disease

Clinical Effectiveness Unit

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ABBREVIATIONS USED

BMD	bone mineral density
BNF	*British National Formulary*
CEU	Clinical Effectiveness Unit
CHC	combined hormonal contraception
CHD	congenital heart disease
CI	confidence interval
COC	combined oral contraception/contraceptive
CTP	combined transdermal patch
Cu-IUD	copper intrauterine device
CVD	cardiovascular disease
CVR	combined vaginal ring
DMPA	depot medroxyprogesterone acetate
EC	emergency contraception
FSRH	Faculty of Sexual & Reproductive Healthcare
HMB	heavy menstrual bleeding
HRT	hormone replacement therapy
INR	international normalised ratio
IUD	intrauterine device
LARC	long-acting reversible contraception/contraceptive
LNG	levonorgestrel
LNG-IUS	levonorgestrel intrauterine system
LQTS	long QT syndrome
LVEF	left ventricular ejection fraction
MET	metabolic equivalent
MI	myocardial infarction
NET-EN	norethisterone enantate
NICE	National Institute for Health and Care Excellence
OR	odds ratio
PID	pelvic inflammatory disease
POP	progestogen-only pill
PPCM	peripartum cardiomyopathy
RCOG	Royal College of Obstetricians and Gynaecologists
SPC	Summary of Product Characteristics
STI	sexually transmitted infection
UKMEC	UK Medical Eligibility Criteria for Contraceptive Use
UPA	ulipristal acetate

GRADING OF RECOMMENDATIONS

A Evidence based on randomised controlled trials

B Evidence based on other robust experimental or observational studies

C Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

✓ Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the guideline group

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SUMMARY OF KEY RECOMMENDATIONS

✓ A proactive approach to contraceptive advice and preconception information should be started in adolescence at age 12–15 years, depending on individual maturity. This should be a standard part of transition from paediatric to adult services.

✓ At transition, cardiologists should provide women and their general practitioner with information that may be relevant to future care including risks associated with contraception and pregnancy. Women should be advised to carry the information when attending other health services.

B Use of combined hormonal contraception is associated with an increased risk of venous thromboembolism (VTE).

B There are limited data on which to draw conclusions about an association between VTE and progestogen-only contraceptive use; a causal association has not been demonstrated.

C Prophylactic antibiotics are not routinely required for the insertion or removal of intrauterine contraception in women with an increased risk of infective endocarditis.

C Vasovagal reactions may occur as a result of cervical stimulation during insertion or removal of intrauterine methods.

C Use of the desogestrel progestogen-only pill may be considered as an interim method while seeking advice about appropriate contraception, except for women on enzyme-inducing medication.

✓ For women with cardiac disease the decision to use intrauterine contraception should involve a cardiologist. The intrauterine method should be fitted in a hospital setting if vasovagal reaction presents a particularly high risk, for example, women with single ventricle circulation, Eisenmenger's physiology, tachycardia or pre-existing bradycardia.

✓ In women on anticoagulant therapy the risk of bleeding complications during insertion of a progestogen-only implant, injectable or intrauterine method is small and should not restrict use of these methods. An experienced clinician should perform the procedure.

✓ Women with cardiac disease should have the opportunity to discuss the risks of continuing an unintended pregnancy and should be informed about the availability of abortion. If a decision to terminate a pregnancy is reached, it is important to avoid unnecessary delays in referral or treatment.

C Women and their partners should be given the opportunity to discuss sexual activity or sexual function and to have any concerns addressed.

C Most individuals with cardiac disease can be reassured that the risk of having a cardiovascular event as a result of sexual activity is very low.

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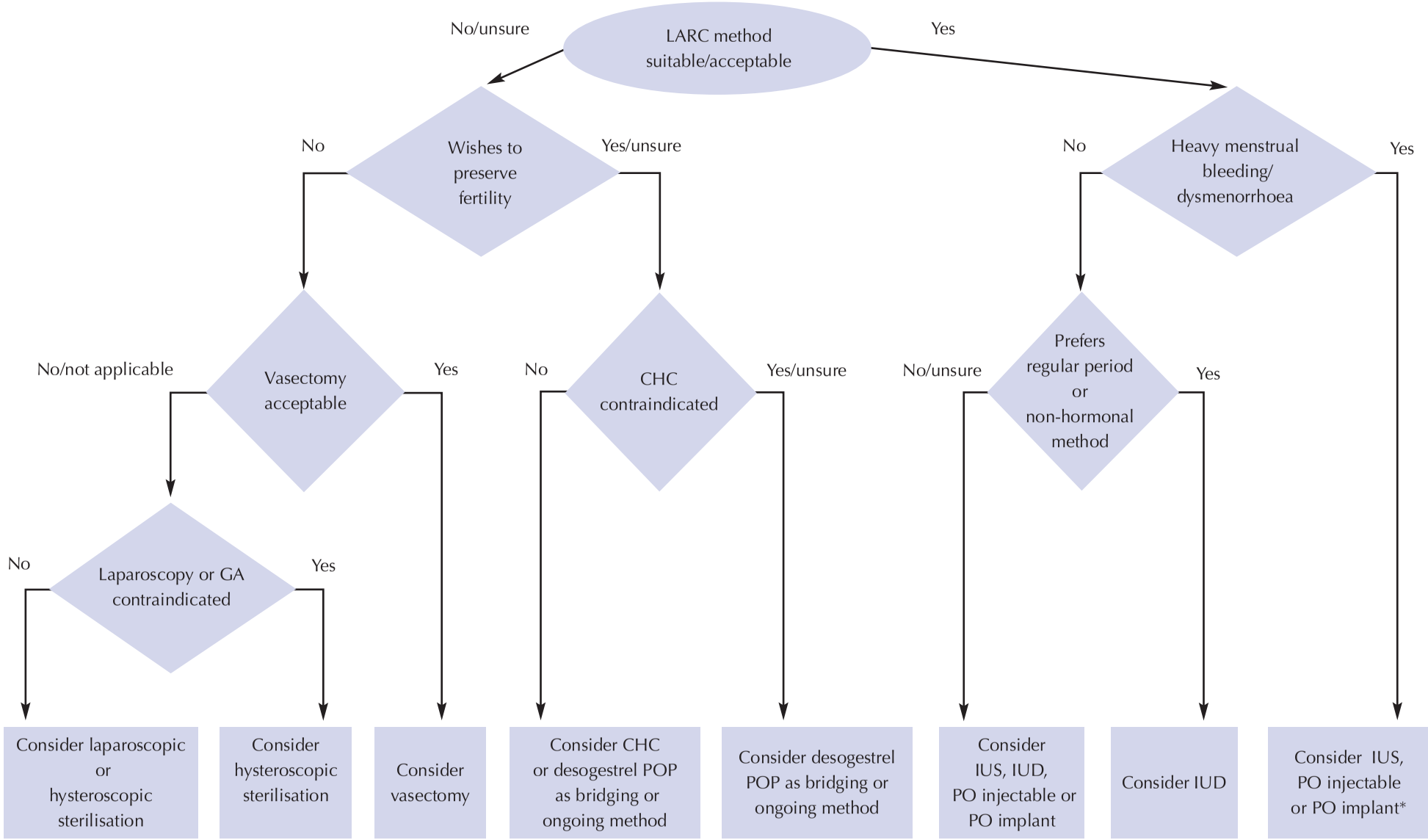
Algorithm 1: Guide to Contraceptive Decision-making in Women with Cardiac Disease

*The progestogen-only implant is less likely to alleviate heavy menstrual bleeding but the bleeding pattern may be acceptable to some women. CHC, combined hormonal contraception; GA, general anaesthesia; IUD, intrauterine device; IUS, intrauterine system; LARC, long-acting reversible contraception; PO, progestogen-only; POP, progestogen-only pill.



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Faculty of Sexual & Reproductive Healthcare Clinical Effectiveness Unit

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FSRH Guidance (June 2014)

Contraceptive Choices for Women with Cardiac Disease

(Revision due by June 2019)

1 Purpose and Scope

This guidance document is intended for UK health professionals providing contraceptive advice to women with cardiac disease. Typical settings where this may occur include cardiac clinics, general practice, contraception services, integrated sexual health clinics, antenatal clinics, postnatal wards, abortion services, and community pharmacies. The guidance covers cardiac conditions affecting women of child-bearing age, including congenital cardiac abnormalities, inherited conditions and acquired (e.g. ischaemic) heart disease. Cerebrovascular disease and venous thromboembolism (VTE) are discussed only in the context of cardiac disease complications.

Key considerations are:

- Cardiac conditions associated with high risk in pregnancy
- Range of contraceptive options and the associated risks and benefits for women with cardiac disease
- Management of cardiac patients undergoing invasive contraceptive procedures and abortion
- Decision-making algorithms and care pathways
- Safety of sexual activity and problems with sexual function in men and women affected by cardiac disease.

This is a new guidance document. Previous guidance[1] on the risk of contraception and pregnancy in heart disease was published by a UK working group in 2006. Updated Medical Eligibility Criteria (MEC) for Contraceptive Use were published by the World Health Organization (WHO)[2] and the Faculty of Sexual & Reproductive Healthcare (FSRH) in 2009.[3]

In developing this guidance, it has not been possible to make recommendations for specific congenital cardiac conditions because of inter-individual variation in the complexity and severity of disease. Instead, guiding principles have been developed with the aim of facilitating multidisciplinary communication and decision-making. Recommendations are based on current evidence and consensus opinion of experts. They may be used to guide clinical practice but they are not intended to serve alone as a standard of medical care or to replace clinical judgement in the management of individual cases. A key to the grading of recommendations is provided on the inside front cover of this document. Details of the methods used by the Clinical Effectiveness Unit (CEU) in developing this guidance are outlined in Appendix 1 and in the CEU section of the FSRH website (www.fsrh.org).

Further information on contraceptive options for women with cardiovascular risk factors or other medical conditions can be found in the UK Medical Eligibility Criteria for Contraceptive Use (UKMEC)[3] and FSRH method-specific guidance.[4–9] Guidance on the management of cardiac disease in pregnancy has been published by the Royal College of Obstetricians and Gynaecologists (RCOG).[10]

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2 Why is it Important to Address Sexual and Reproductive Health Issues in Women with Cardiac Disease?

Increasing numbers of women of reproductive age are affected by cardiac disease, partly because more children with congenital heart disease (CHD) are surviving to adulthood and also because of the rise in obesity and unhealthy behaviours.

Pregnancy is associated with haemodynamic, haemostatic and metabolic alterations that increase cardiovascular risk, particularly in women with cardiac disease.[11] Cardiac disease is the leading cause of maternal death in pregnancy in the UK,[12] and there is also a higher risk of complications for the fetus such as preterm delivery, CHD, growth restriction, stillbirth or death in infancy.[13,14]

The risks associated with pregnancy vary widely and depend not only on a woman's cardiac diagnosis but also on individual factors (see section on risk associated with pregnancy on page 9). For some women with cardiac disease the risks associated with pregnancy are no different to those of the general population; for others the risk of morbidity or mortality associated with pregnancy is higher. In the past the risk of maternal death in women with pulmonary hypertension was reported to be as high as 30–50%.[15,16] More recent data[16,17] suggest that outcomes are improving; however, pregnancy is still considered to present an unacceptable health risk for some women.[18] Provision of information and effective contraception are therefore of paramount importance to avoid pregnancy or to allow time for preconception planning and minimisation of pregnancy risks.

Choosing the most appropriate contraceptive for women with cardiac disease requires consideration of the level of risk should the woman become pregnant; the method's efficacy; the risks associated with administration and long-term use; the contraceptive benefits; and the woman's own personal choice. In many cases, balancing these risks will require a multidisciplinary and individualised approach.

People with cardiac disease may also experience sexual problems because of their condition or treatment. They and/or their partners may be concerned about sexual activity and the risks to their health (see page 13). Sexual function can affect quality of life and therefore it is important that individuals and/or their partners are given the opportunity to discuss any problems.

3 When Should Sexual and Reproductive Health Issues be Raised?

Young people with cardiac disease have reported concerns about their fertility, genetic transmission of their condition and the effect of pregnancy on their health,[19] yet many have limited knowledge about sexual and reproductive health.[20] Adults with cardiac disease have also been shown to have information gaps, to use less effective methods, and to have been incorrectly advised on contraception.[21–23]

Children with CHD will usually be seen in a congenital cardiac centre. Links between the cardiac centre and the patient should ideally be established from a young age and maintained so that the young person can be educated about their disease and, where necessary, information can be passed on to other health professionals. The transition process from paediatric to adult services should routinely include provision of information about the significance of the individual's cardiac disease in terms of pregnancy, contraception and sexual function. The age at which this is initiated should be judged according to the individual's level of maturity but will generally be between the ages of 12 and 15 years.

In law, any competent young person in the UK can consent to medical treatment.[24,25] Under-16-year-olds should be advised to inform their parent/carer(s) of sexual activity and contraceptive use but contraception can be supplied without parental knowledge providing the young person understands the information provided and contraception use is judged to be in their best interests.[24,25] Further information is available in FSRH guidance on *Contraceptive Choices for Young People*.[26]

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At transition cardiologists should provide women and their general practitioner with:

- A summary of the woman's condition and medication
- Risk associated with pregnancy
- Risks of thrombosis, severe vasovagal reaction and endocarditis
- Any contraceptive methods that are absolutely contraindicated
- Follow-up arrangements
- Consultant's contact details.

Women should be advised to carry the information when attending other health services.

Women diagnosed with acquired cardiac disease in their reproductive years should be provided with information about contraception (see contraception decision-making section on page 7 and Appendix 2) and, where appropriate, women with acquired disease should be given the opportunity to discuss sexual health issues affected by their condition.

✓ A proactive approach to contraceptive advice and preconception information should be started in adolescence at age 12–15 years, depending on individual maturity. This should be a standard part of transition from paediatric to adult services.

✓ At transition, cardiologists should provide women and their general practitioner with information that may be relevant to future care including risks associated with contraception and pregnancy. Women should be advised to carry the information when attending other health services.

4 What Should be Covered in a Consultation?

A detailed history and risk assessment is required before prescribing contraception.[27,28] For all women, history taking should include:

- Medical conditions (past and present) and procedures
- Menstrual and gynaecological history including cervical screening
- Obstetric history
- Family history of medical conditions
- Drug history (prescription, non-prescription, herbal remedies and supplements)
- Sexual history
- Specific enquiry about cardiovascular and cerebrovascular risk factors
  - migraine
  - smoking
  - personal or family history of hypertension, VTE, thrombophilia, hyperlipidaemia, stroke or diabetes.

For those with cardiac conditions, a clinician should also seek to enquire specifically about:

- Cardiac diagnosis, cardiac operations or catheter interventions
- History of rhythm disturbance
- Functional status, for example, history of breathlessness, fatigue, oedema, presyncope/syncope (New York Heart Association Classification)[29]
- Advice of the woman's cardiologist on use of estrogen and degree of risk associated with pregnancy.

A recording of blood pressure, weight and body mass index should be documented. It may also be appropriate to review recent cardiac clinic correspondence and results if this information is accessible and the patient consents.

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5 Contraceptive Risks of Relevance to Cardiac Patients

Very few studies have looked at the safety of contraceptive use in patients with cardiac conditions. Evidence must therefore be extrapolated from generally 'healthy' populations. Even a small degree of risk in 'healthy' patients may be significant for those with cardiac disease and predisposing risk factors.

5.1 Combined hormonal contraception

Estrogen-containing contraceptive methods, known as combined hormonal contraception (CHC), include the combined oral contraceptive pill (COC), combined transdermal patch (CTP) and combined vaginal ring (CVR). A combined injectable method exists but is not currently available in the UK.

In terms of cardiovascular and cerebrovascular health, the risks associated with CHC relate mainly to an increased risk of thrombosis.[30–32]

CHC can also cause blood pressure elevation and fluid retention which may exacerbate cardiac disease.[33]

5.1.1 Risk of VTE

The risk of VTE amongst COC users is approximately twice that of non-users (average risk across all brands studied of 9–10/10 000 woman-years).[34] There has been much debate about whether the type of progestogen influences the level of risk. COCs containing desogestrel, gestodene, drospirenone and cyproterone acetate appear to be associated with a higher risk of VTE than those containing levonorgestrel, norethisterone and norgestimate.[4,35] Contrary to evidence on combined hormone replacement therapy (HRT) preparations, administration of CHC by non-oral routes does not appear to reduce VTE risk, as might be expected, through avoidance of first-pass metabolism; in fact there is possibly a greater risk of VTE with non-oral CHC preparations than with the COC.[36–40]

5.1.2 Ischaemic heart disease

Some studies have reported an increased risk of myocardial infarction (MI) in CHC users[41–44] whereas others have not.[45,46] Data from a pooled analysis of 11 studies reported an increased risk of MI with use of COCs [pooled odds ratio (OR) 1.7; 95% confidence interval (95% CI) 1.2–2.3]. However, a meta-analysis of eight included studies found no associated increased risk of MI with use of oral contraceptives (OR 1.34; 95% CI 0.87–2.08).[47] Risk may be partly influenced by independent risk factors for MI such as smoking, hypertension, hypercholesterolaemia and diabetes.[48–50] No difference in risk has been observed by progestogen type.[35]

5.1.3 Cerebrovascular disease

An increased risk of stroke has been reported in COC users with migraine compared with COC users without migraine.[51–56] However, a subsequent meta-analysis has reported that this increased risk appears only to affect women who experience migraine with aura, and that oral contraceptive use in these individuals further increases their risk of ischaemic stroke.[57]

The association between COC users and stroke in other women is less clear. A meta-analysis reported a two-fold increase in risk of ischaemic stroke with use of low-dose COCs.[43] However, other studies have not found that COC use results in a statistically significant increased risk of ischaemic[58,59] or haemorrhagic stroke.[51,59]

B Use of combined hormonal contraception is associated with an increased risk of venous thromboembolism.

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5.2 Progestogen-only contraceptives

Few studies have been large enough to evaluate the risk of CVD associated with use of progestogen-only contraceptives. The majority of available evidence suggests that there is no increased risk of thrombosis,[40,60] although a statistically significant increased risk of VTE with use of the progestogen-only injectable has been reported.[60,61] This finding may be the result of confounding and bias, and more research is needed to confirm any association.

There are potentially significant differences between the injectable preparations, depot medroxyprogesterone acetate (DMPA) and norethisterone enantate (NET-EN), and other progestogen-only methods. The injectable methods deliver a higher dose of progestogen and are associated with adverse effects on lipid profiles.[62,63] The significance of these changes is not fully understood and there is evidence to suggest that the effects are transient, even with continued use of the injectable.[63]

Other potentially relevant effects of the progestogen-only injectable are weight gain and loss of bone mineral density (BMD).[6,64] The health implications of BMD loss are unclear as bone density recovers upon cessation of the injectable and an increased risk of fracture has not been demonstrated.[6]

B There are limited data on which to draw conclusions about an association between VTE and progestogen-only contraceptive use; a causal association has not been demonstrated.

5.3 Intrauterine methods

5.3.1 Infection

Insertion of a copper intrauterine device (Cu-IUD) or levonorgestrel intrauterine system (LNG-IUS) may induce bacterial spread, potentially leading to upper genital tract and/or systemic infection. There is a lack of good-quality data relating to the risk of pelvic inflammatory disease (PID) and use of intrauterine methods.[65] Data from a large retrospective study suggest that the risk is low, even in those not screened for chlamydia or gonorrhoea prior to insertion.[66] Compared with non-users, an increased risk of PID has been demonstrated in the first 20 days after IUD insertion.[67] In the presence of sexually transmitted infection (STI) the risk of infection is increased at any time during use of intrauterine methods. It has been suggested that the risk of infection may be lower with use of the LNG-IUS because progestogen increases the barrier function of cervical mucus.[68] Current evidence[68] is of low quality and any difference in risk between LNG-IUS and Cu-IUD users has yet to be substantiated.

All women should be offered screening and treatment for STI infection prior to insertion of an intrauterine method. A Cochrane review[69] examining the effectiveness of prophylactic antibiotic administration, in reducing IUD-related complications and discontinuations within 3 months of insertion, concluded that the risk of IUD-related infections is low with or without antibiotic prophylaxis. There may be some benefits in terms of reducing unscheduled return visits but there was limited evidence to suggest giving prophylactic antibiotics (doxycycline or azithromycin) was cost effective.

There has been theoretical concern about IUD insertion in women who are at increased risk of infective endocarditis (see Section 6.3 on page 8). Previously antibiotic prophylaxis was advised for such patients.[5] The risk of infective endocarditis in at-risk women following intrauterine contraceptive insertion or removal is unknown. In a small clinical trial, 13% of women were identified as having transient bacteraemia from vaginal organisms within 10 minutes of removal and replacement of intrauterine contraception.[70] One case report was identified that reported

infective endocarditis in a woman with valvular heart disease following insertion of an IUD.[71] No antibiotic prophylaxis was given at the time of insertion and the device was spontaneously expelled prior to onset of symptoms.

A review by the National Institute for Health and Care Excellence (NICE)[72] found no evidence to link level, frequency and duration of bacteraemia with the development of infective endocarditis. Moreover, the evidence did not show a causal relationship between having an interventional procedure and the development of infective endocarditis. Therefore, NICE no longer recommends routinely offering antibiotic prophylaxis for defined interventional procedures such as IUD insertion, unless there is suspected infection at the site of the procedure.[72,73] Preliminary data suggest that trends in rates of infective endocarditis in England have not significantly altered since 2008 when advice on antibiotic prophylaxis changed.[74]

C Prophylactic antibiotics are not routinely required for the insertion or removal of intrauterine contraception in women with an increased risk of infective endocarditis.

5.3.2 *Vasovagal reactions*

Cervical stimulation during the insertion of intrauterine methods can cause a vasovagal reaction, bradycardia and other arrhythmias.[75–77] In healthy women vasovagal incidents usually resolve with simple resuscitation measures; rarely bradycardia persists and requires treatment with intravenous atropine.[78] Some women with cardiac disease may be at increased risk because they may not respond to standard treatment measures in the same way (see Section 6.2 on page 8).

C Vasovagal reactions may occur as a result of cervical stimulation during insertion or removal of intrauterine methods.

5.4 Sterilisation

Female sterilisation involves occlusion of the Fallopian tubes and is intended to be permanent. The procedure can be carried out by laparoscopy, mini-laparotomy, hysteroscopy or at the time of Caesarean section.[79,80] Women with cardiac disease have a higher risk of general anaesthetic complications and they may be less able to compensate for physiological changes that occur during laparoscopy. For all women there is risk of major complications, for example, injuries to the bowel, bladder or blood vessels, which require laparotomy.[81] The risk of conversion to laparotomy is approximately 1.9/1000 procedures.[81]

Laparoscopic tubal occlusion has a lifetime failure rate of 1 in 200 and is less effective than the progestogen-only implant and vasectomy (Appendix 3).[82] Vasectomy is also associated with a lower risk of major complications than laparoscopic tubal occlusion.[79]

Hysteroscopic sterilisation is a newer technique, which can be performed without the need for general anaesthetic. This technique has been approved by NICE[80] and has been successfully undertaken in women with severe cardiac disease.[83] It is irreversible and contraception must be continued for at least 3 months until successful occlusion is confirmed by ultrasound scan or hysterosalpingogram (HSG). The failure rate has been reported as 1 in 500 at 5 years of follow-up.[84] A large cohort study investigating complications associated with hysteroscopic sterilisation reported that approximately 2% of women experienced a vasovagal response.[85]

Updated guidance on sterilisation is due to be published in 2014 (refer to the FSRH website at www.fsrh.org).

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6 Contraceptive Decision-making and Special Measures for Women with Cardiac Disease

A list of contraceptive methods and their efficacy, mode of action, advantages and disadvantages is provided in Appendix 3. More detailed information can be found in FSRH method-specific guidance.[4–7,79,86–88]

Factors affecting contraceptive choice are highlighted in Box 1. Key considerations are an individual's risk of thrombosis, severe vasovagal reaction or infective endocarditis. The risks of using a particular method should be balanced with how important it is for that individual to avoid pregnancy, how effective the method is, and whether it provides non-contraceptive benefits.

Box 1 Factors affecting contraceptive choice

- Individual patient choice
- Risk of thrombosis/thromboembolism
- Risk of severe vasovagal reaction
- Risk of infective endocarditis
- Risk associated with pregnancy
- Anticoagulation and risk of heavy menstrual bleeding
- Non-contraceptive benefits (e.g. reduced menstrual bleeding)
- Drug interactions with medication
- Surgery and/or immobilisation
- Efficacy of method (particularly important if pregnancy is not advisable)
- Thrombotic risks of estrogen-containing (combined) contraceptives
- Hypertensive risks of estrogen-containing (combined) contraceptives
- Infective risks associated with insertion and use of intrauterine methods
- Risk of vagal stimulation and bradycardia during intrauterine method insertion
- Bleeding risks associated with contraceptive procedures in women on anticoagulant therapy

Eligibility criteria (page 9) can be used to guide the decision process.[3] However, because of inter-individual variation in the complexity and severity of cardiac conditions, the guideline development group was of the opinion that eligibility criteria were too simplistic to be used as the sole consideration. Similarly, the indicators of low risk listed in Box 2 may be helpful, but where there is any doubt about the safety of a method, particularly combined or intrauterine methods, clinicians are advised to discuss this with the cardiology team.

Box 2 Indicators of low-risk cardiac conditions

Low risk is indicated by the presence of all of the following:

- Patient discharged from cardiology follow-up or seen at intervals of 2 years or more
- Oxygen saturation normal
- Patient not on cardiac medications, including aspirin

While seeking advice, use of a progestogen-only pill (POP) containing 75 µg desogestrel (e.g. Cerazette®, Cerelle®) is likely to be safe in most cases as an interim 'bridging' method, except for women on enzyme-inducing medication, for example, bosentan. The CEU recommends the desogestrel POP because it suppresses ovulation more consistently and has a longer window period for missed pills (12 vs 3 hours for other POPs). Continuous daily administration without a break should be emphasised, in addition to advice on double protection with condoms, and emergency contraception (EC) (see Algorithm 1 on page iv).

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C Use of the desogestrel progestogen-only pill may be considered as an interim method while seeking advice about appropriate contraception, except for women on enzyme-inducing medication.

6.1 Cardiac patients at increased risk of thrombosis/thromboembolism

Stasis, endothelial injury and hyperviscosity (Virchow's triad) increase the risk of clot formation. Impaired cardiac function and/or dilated heart chambers or arrhythmia increase the risk of stasis. Closure of a cardiac defect within the last 6 months or presence of a mechanical heart valve increase the risk of thrombus formation. Cyanotic defects are associated with hyperviscosity because of increased haemoglobin.

Women with right-to-left shunts due to cyanotic heart disease or pulmonary arteriovenous malformations are at risk of paradoxical embolism and stroke if they develop venous thrombosis; therefore use of CHC is not recommended. Although an uncomplicated, unoperated atrial septal defect results in left-to-right shunting, it is possible to reverse the shunt with simple physiological manoeuvres (e.g. Valsalva). Therefore women with atrial septal defect should also consider other forms of contraception, especially if they have additional risk factors for thromboembolism.

Patent foramen ovale occurs in 10–20% of the population but is usually undetected. It may be diagnosed on investigation of a clinical event such as embolic stroke, in which case CHC would not be recommended.

6.2 Cardiac patients at risk of severe vasovagal reaction

Vasovagal reaction represents a particularly serious risk for women with cardiac conditions such as single ventricle (e.g. Fontan) circulation or Eisenmenger's physiology (see section on pulmonary hypertension on page 11). These patients may also be at very high risk if they become pregnant, so the risk of IUD/IUS insertion must be balanced against the risks associated with pregnancy. Women with arrhythmias can also experience vasovagal collapse because the heart rate is too fast to allow ventricular filling or too slow to facilitate adequate outflow. Women with cardiac disease who are at increased risk from vasovagal reaction should have intrauterine contraception fitted in a hospital setting.

✓ For women with cardiac disease the decision to use intrauterine contraception should involve a cardiologist. The intrauterine method should be fitted in a hospital setting if vasovagal reaction presents a particularly high risk, for example, women with single ventricle circulation, Eisenmenger's physiology, tachycardia or pre-existing bradycardia.

6.3 Cardiac patients at risk of infective endocarditis

As discussed in the section on IUDs and infection on page 5, invasive contraceptive procedures may theoretically increase the risk of infective endocarditis. Prophylactic antibiotics are no longer recommended routinely because they have not been shown to affect rates of endocarditis, but this does not necessarily mean that there is no risk. Clinicians should liaise with a woman's cardiologist to discuss whether insertion of an intrauterine method is appropriate. The risk of developing infective endocarditis is increased in those with:

- Valvular heart disease
- Valve replacement
- Structural CHD, including surgically corrected or palliated structural conditions, but excluding isolated atrial septal defect, fully repaired ventricular septal defect or fully repaired patent ductus arteriosus, and closure devices that are judged to be endothelialised
- Hypertrophic cardiomyopathy
- Previous infective endocarditis.

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6.4 Eligibility criteria

UKMEC[3] is a set of evidence-based recommendations on the use of contraceptive methods in the presence of different medical and social factors. Health professionals should be familiar with the most recent version of UKMEC and refer to this document when assessing a woman's eligibility for a contraceptive method.

Appendix 2 lists the definitions for the different UKMEC categories. Categories 1–4 apply to hormonal and non-hormonal methods of contraception. Appendix 2 also shows the categories for cardiac conditions and for related conditions.

UKMEC provides recommendations for the use of contraceptives in the presence of risk factors for acquired heart disease, for example, obesity, smoking and ischaemic heart disease. In addition it provides some categorisation of valvular disease and CHD. Differentiation is made between uncomplicated and complicated conditions, for example, by pulmonary hypertension, atrial fibrillation, or history of endocarditis. Appendix 2 summarises current UKMEC categories for cardiac-related conditions.

Unless specifically stated, UKMEC does not take account of multiple conditions. There are no rules for combining multiple categories. Assessing a person's eligibility in the presence of multiple medical and social factors will require clinical judgement and balancing of risks and benefits.

For women with a history of severe cardiovascular complications (i.e. ischaemic heart disease, cerebrovascular attack or other thromboembolic conditions) the use of the Cu-IUD for EC or LNG for EC is a UKMEC 1. There are currently no UKMEC categories available for ulipristal acetate (UPA) due to the newness of the product, however cardiac disease is not listed as a contraindication to use within the Summary of Product Characteristics (SPC).[89]

6.5 Risk associated with pregnancy

The degree of risk associated with pregnancy in women with cardiac disease will depend on the nature of the condition and on factors such as valvular function, cardiac rhythm, pulmonary pressure, chamber enlargement, size of aorta, cyanosis, previous intervention, cardiac medication and lifestyle factors. In 2006, Thorne *et al*.[1] modified the WHO classifications for contraception use to stratify risk associated with pregnancy in women with heart disease. This was recently modified by the European Society of Cardiology and modified further by the CEU (Appendix 4). Conditions in which there is pulmonary hypertension confer greater risk in pregnancy than most other conditions (see section on pulmonary hypertension on page 11).

While cardiac disease is not a contraindication to the use of barrier methods or natural family planning, their higher rates of failure with typical use compared to other methods[82] may make them inappropriate for women with conditions where pregnancy presents an unacceptable risk.

There is good evidence that long-acting reversible contraception (LARC) methods (i.e. those that require administration less than once per cycle or month) have lower typical use failure rates than short-acting methods such as contraceptive pills.[82,90] This is because the efficacy of LARC (i.e. the progestogen-only injectable, progestogen-only implant and intrauterine methods) is less dependent on the user. NICE guidance on LARC (2005)[64] highlights the superior cost-effectiveness of LARC methods after only 1 year of use and recommends increased use of LARC as a means of reducing unintended pregnancies (Box 3).

Box 3 Considerations for reducing the risk of unintended pregnancy

- Advance provision of emergency contraception
- Awareness of the emergency copper intrauterine device
- Long-acting reversible contraception and sterilisation are the most effective methods
- Dual use of condoms with other contraceptive method
- Condom demonstrations and information regarding free supplies
- Diaphragms, caps and fertility awareness methods are not considered sufficiently effective
- Sole use of condoms not advisable, particularly if pregnancy poses a high risk to health

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6.6 Anticoagulation and risk of bleeding

Insertion of the progestogen-only implant, injectable or intrauterine methods is associated with a small risk of bleeding. Available evidence suggests that even in women who are anticoagulated, the risk of bleeding from administration of these methods does not pose an unacceptable health risk.[3,75,76] The CEU would advise ensuring that coagulation has been monitored recently. There is generally no need to alter anticoagulant therapy if the patient is anticoagulated within the target therapeutic range. A community setting is generally appropriate providing there are no other risks (e.g. severe vasovagal reaction). However, it is recommended that an experienced clinician performs the procedure with careful attention to haemostasis and application of a pressure bandage following implant procedures. Subcutaneous administration of the progestogen-only injectable (Sayana-Press®) can be considered as an alternative to intramuscular injection, although any advantage in terms of bleeding is currently unproven. There is no need to increase monitoring of anticoagulation after initiation of contraception (see medication section below).

✓ In women on anticoagulant therapy the risk of bleeding complications during insertion of a progestogen-only implant, injectable or intrauterine method is small and should not restrict use of these methods. An experienced clinician should perform the procedure.

6.7 Non-contraceptive benefits

Heavy menstrual bleeding (HMB) may be a problem in women on anticoagulation therapy.[76,77,91] HMB and any resulting or worsening anaemia could lead to cardiac complications in some patients, for example, those with heart failure. Hormonal contraceptives such as combined hormonal methods, the progestogen-only injectable and the LNG-IUS are noted as possible therapies for the management of HMB.[76,92] There is a trend towards amenorrhoea/infrequent bleeding with use of the progestogen-only injectable[93,94] and also the LNG-IUS.[95] The LNG-IUS is licensed for the management of idiopathic HMB. Conversely, altered bleeding patterns including increased bleeding can be a side effect of hormonal methods, particularly progestogen-only contraceptives.

6.8 Medication

Serum levels of contraceptive hormones may be increased or decreased by concomitant drug use and hormonal contraceptives may themselves increase or decrease serum levels of concomitant drugs.[96] Specific interactions that may be relevant to women with cardiac disease are listed in Appendix 5.

Progestogens have been reported to affect international normalised ratio (INR) levels in warfarinised women. A true interaction has not been demonstrated and seems unlikely given that both elevation and reduction in INR have been reported. The CEU advises that women on warfarin therapy continue to be monitored as usual following initiation of hormonal contraception. For further information on drug interactions health professionals can refer to FSRH drug interactions guidance,[96] *the British National Formulary* (BNF)[97], *Stockley's Drug Interactions*[98] and the individual drug's SPC.[99]

Macrolides (e.g. azithromycin) which are used in the management of STIs should be used with caution in those with long QT syndrome (LQTS).[100,101]

Caution is also advised when using local anaesthetics in those with impaired cardiac conduction or cardiovascular disease.[100] The use of local anaesthesia in combination with adrenaline is not advised.[100]

6.9 Surgery and/or immobilisation

Immobilisation and surgery are independent risk factors for VTE. As CHC is also a risk factor for VTE[46–49,63–74,78,79] it is generally advised that women who are undergoing major elective surgery, where immobilisation is expected, stop CHC at least 4 weeks before the surgery and use an

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alternative method.[3] Major surgery with prolonged immobilisation is a UKMEC 4. When the use of CHC has not been discontinued at least 4 weeks before major surgery with immobilisation (e.g. in an emergency procedure) thromboprophylaxis guidelines should be followed.[102,103] This includes the use of mechanical or pharmacological thromboprophylaxis. Progestogen-only contraceptives do not appear to increase the risk of VTE and are therefore an appropriate alternative for women undergoing surgery, providing there are no other factors that would restrict their use.

CHC does not need to be discontinued before minor surgery without immobilisation (UKMEC 1).[3] Use of CHCs in women undergoing major surgery without immobilisation is a UKMEC 2. Thromboprophylaxis or switching to a progestogen-only or non-hormonal method may need to be considered depending on the individual woman's circumstances and other risk factors.

Algorithm 1 on page iv is intended to guide clinicians and women with cardiac disease through the decision-making processes involved in choosing a suitable contraceptive method. It should be used in conjunction with the considerations and UKMEC categories discussed earlier.

7 Specific Conditions and Complications

7.1 Pulmonary hypertension

Pulmonary hypertension can be primary (idiopathic) or secondary to other medical conditions. Right heart catheterisation is required to confirm the diagnosis. Eisenmenger's syndrome is a cyanotic heart defect in which a long-standing left-to-right intracardiac shunt causes pulmonary hypertension and eventually reverses to a right-to-left shunt. The syndrome can develop secondary to ventricular septal defect, patent ductus arteriosus or, less commonly, atrial septal defect.

The haemodynamic adaptations in pregnancy are poorly tolerated by women with pulmonary hypertension, particularly in the peripartum period. Historically the maternal mortality rate was reported to be 30–50%.[15] Recent case series have reported improved pregnancy outcomes of 25% maternal mortality or less.[16,17] Although the prognosis has improved, pregnancy may still be considered an unacceptable risk for some women with pulmonary hypertension.[104]

7.2 Arrhythmias

There is a lack of evidence on the effects of hormonal contraceptives on cardiac rhythm. Because of the potential increased risk of thrombosis, CHC is generally not recommended for women who are at risk of thrombosis from cardiac arrhythmias such as atrial fibrillation, particularly if the woman is not on anticoagulant treatment.

The safety of hormonal contraceptives is unclear with regard to conditions such as Brugada syndrome and congenital or acquired (drug-induced) LQTS, which are associated with arrhythmia and sudden cardiac death. Women have a lifelong higher risk of sudden cardiac death associated with LQTS than men. Sex hormones are thought to play a role by influencing the regulation of cardiac ion channels. There is evidence to suggest that the QT interval is prolonged by endogenous estrogen and estrogen-only HRT, whereas combined estrogen and progestogen HRT has been shown to have no significant effect.[105,106] No studies were identified in relation to the effects of hormonal contraceptives, and there is no specific contraindication to the use of CHC in women with congenital familial or acquired arrhythmias.

7.3 Peripartum cardiomyopathy

Peripartum cardiomyopathy (PPCM) typically starts during the last month of pregnancy or up to 6 months after delivery.[107] There is limited knowledge about the risk during subsequent pregnancies. A working group of the Heart Failure Association of the European Society of Cardiology has produced a statement on PPCM.[107] The group advises that subsequent pregnancy is not advised for women with a left ventricular ejection fraction (LVEF) of less than

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25% at diagnosis or for whom LEVF has not normalised. The group indicate that all women with a history of PPCM should be advised that pregnancy may negatively affect cardiac function and can result in heart failure and possibly death.[107] The statement[107] advises against the use of CHC in women with a history of PPCM and warns that consideration is given to the risks of general anaesthetic in those who continue to experience severe dysfunction of the left ventricle.

7.4 Heart transplantation

As a general rule, pregnancy should be avoided for at least 1 year following solid organ transplantation.[108] Contraceptive decisions for women who have undergone heart transplants should take account of immunosuppression, drug interactions with medication, and any residual complications from their cardiac disease.

The US Medical Eligibility Criteria for Contraceptive Use[109] (USMEC) has categories for women who have undergone solid organ transplants. If the transplant is uncomplicated then the benefits of using all methods generally outweigh the theoretical or proven risks (USMEC 2). For those with post-transplant complications CHC use is a USMEC 4 (i.e. the condition represents an unacceptable health risk) and initiation of intrauterine methods is a USMEC 3 (i.e. a condition where the theoretical or proven risks generally outweigh the advantages of using the method). All other methods are a USMEC 2, as is continuation of intrauterine contraception in the presence of complications.

Data are lacking with regard to risk of infection from use of intrauterine methods in women who have undergone a transplant but evidence extrapolated from LNG-IUS use in the HIV population is reassuring.[110]

7.5 Ischaemic heart disease

Ischaemic heart disease is uncommon in women of reproductive age but it has been an increasing cause of maternal death in the UK over the past decade.[10] With the increasing age and fertility of mothers, the incidence of coronary artery disease in pregnancy is likely to increase. Although previous MI is not an absolute contraindication to pregnancy, patients are potentially at risk of further ischaemia and left ventricular dysfunction, and careful evaluation is required before conception.

In women with a personal history of ischaemic heart disease, CHC is associated with an unacceptable risk (UKMEC 4). The UKMEC categories for other methods of contraception are given in Appendix 2. Sexual function in women with ischaemic heart disease is covered on page 13.

8 Pregnancy

8.1 Preconception planning

Women with cardiac disease who wish to conceive should be advised to continue contraception until they have seen an obstetrician and cardiologist for preconception advice, ideally in a joint clinic.[111] This allows time to discuss the risks associated with pregnancy, to make any necessary adjustments to medication, to optimise maternal health, and to make plans for management in pregnancy. Once pregnant, RCOG guidelines[10] advise that women with cardiac disease see an obstetrician by 8 weeks' gestation.

8.2 Unintended pregnancy

In Great Britain, abortion is governed by the Abortion Act 1967,[112] as amended by the Human Fertilisation and Embryology Act 1990.[113] Cardiac patients with unintended pregnancy have the option of abortion in England, Wales and Scotland irrespective of the severity of their disease.[112,113] The 1967 Abortion Act does not extend to Northern Ireland, where abortions can only be performed where it is necessary to preserve the life of the woman or there is a real risk of a serious adverse effect on her physical or mental health long-term or permanently.[114,115]

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Women who are unsure whether to have an abortion because of their cardiac disease or medication should be seen urgently by an obstetrician with an interest in cardiac disease.

Pregnancy-related physiological changes such as increased maternal cardiac output begin in the middle of the first trimester, and cardiac risks continue to rise until they peak towards the end of the second trimester.[116] Gestation may also determine choice of procedure. Therefore, once a decision to terminate a pregnancy is reached, it is important that women with cardiac disease are referred and undergo abortion without any unnecessary delay.

For women with cardiac conditions, use of certain abortion drugs may be contraindicated. The safest method of abortion and type of anaesthesia may depend on an individual's condition and cardiac function. Prior to 7 weeks' gestation, medical termination is more effective than surgical procedures.[111] A VTE risk assessment is recommended for all women undergoing a medical or surgical abortion.[111]

The first part of a medical abortion involves administration of mifepristone, a drug that has antiglucocorticoid activity. In theory, women on chronic glucocorticoid therapy, such as those who have undergone a heart transplant, could be at risk of glucocorticoid insufficiency. The SPC for Mifegyne®[117] indicates that the efficacy of corticosteroids may be reduced in the 3–4 days after use of mifepristone and that therapy should be adjusted.

Prostaglandin, usually in the form of vaginal misoprostol, is given as the second part of a medical abortion. It is also commonly used for priming the cervix prior to surgical abortion. CVD is listed as a caution under misoprostol in the BNF,[100] and the SPC[118] advises caution in conditions where hypotension may cause severe complications . For cervical priming, non-pharmacological agents are available as an alternative.

Haemorrhage is an uncommon complication of both medical and surgical abortion.[111] Women on anticoagulants and women with pre-existing anaemia are at greater risk.

✓ Women with cardiac disease should have the opportunity to discuss the risks of continuing an unintended pregnancy and should be informed about the availability of abortion. If a decision to terminate a pregnancy is reached, it is important to avoid unnecessary delays in referral or treatment.

9 Sexual activity, sexual function and cardiac disease

Physiological changes such as increased heart rate, blood pressure and oxygen consumption occur during sexual arousal and sexual activity.[119] Sexual activity can act as a trigger to MI;[120,121] however, the absolute risk attributable to sex is extremely low.[120] Being less physically fit was associated with an increased risk, and regular exercise has been shown to modify the risk of MI associated with sex.[120,121] Recent guidance from the American Heart Association[122] suggests that sexual activity is equivalent to mild to moderate physical activity in the range of 3–5 metabolic equivalents of tasks (METs). A MET is a physiological measure of energy expenditure. One MET is defined as 1 kcal/kg/hour and is equivalent to the energy expenditure during quiet sitting.

It is suggested that individuals who do not experience cardiovascular symptoms when exercise testing at a level equivalent to 6 METs are unlikely to experience such symptoms during sex.[123]

The large majority of individuals with cardiac disease are at low risk and can be advised to initiate or resume sexual activity and/or can be treated for sexual dysfunction.[122,124] Guidance suggests that others, for example, those with moderate angina or within 6 weeks of an MI, may need to undergo some further cardiac evaluation before being reclassified as either low or high risk.[124] For individuals considered to be high risk [for example, congestive heart failure (Class III or IV), very recent MI (<2 weeks) or unstable angina] it is recommended that individuals should be stabilised by specific treatment for their condition[124] before initiating or resuming sexual activity or being treated for sexual dysfunction (Appendix 6).[122,124]

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Phosphodiesterase type-5 inhibitors (sildenafil, tadalafil and vardenafil) are used in the treatment of erectile dysfunction and pulmonary hypertension; they have also been investigated for use in the treatment of sexual dysfunction in women and are sometimes used recreationally by both sexes. According to the BNF,[125] phosphodiesterase inhibitors are contraindicated in:

- Individuals receiving nitrates
- Those for whom vasodilatation or sexual activity are inadvisable
- Hypotension
- Recent stroke
- Unstable angina
- Myocardial infarction.

C Women and their partners should be given the opportunity to discuss sexual activity or sexual function and to have any concerns addressed.

C Most individuals with cardiac disease can be reassured that the risk of having a cardiovascular event as a result of sexual activity is very low.

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APPENDIX 1: DEVELOPMENT OF CEU GUIDANCE

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Declared Interests
No relevant interests were declared.

Clinical Effectiveness Unit (CEU) Guidance is developed in collaboration with the Clinical Effectiveness Committee (CEC) of the Faculty of Sexual & Reproductive Healthcare (FSRH). The CEU Guidance development process employs standard methodology and makes use of systematic literature review and a multidisciplinary group of professionals. The multidisciplinary group is identified by the CEU for their expertise in the topic area and typically includes clinicians working in family planning, sexual and reproductive health care, general practice, other allied specialities, and user representation . In addition, the aim is to include a representative from the FSRH CEC, the FSRH Meetings Committee and FSRH Council in the multidisciplinary group.

Evidence is identified using a systematic literature review and electronic searches are performed for: MEDLINE (CD Ovid version) (1996–2013); EMBASE (1996–2013); PubMed (1996–2013); The Cochrane Library (to 2013) and the US National Guideline Clearing House. The searches are performed using relevant medical subject headings (MeSH), terms and text words . The Cochrane Library is searched for relevant systematic reviews, meta-analyses and controlled trials relevant to contraceptive choices for women with cardiac disease. Previously existing guidelines from the FSRH (formerly the Faculty of family Planning and Reproductive Health Care), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO) and the British Association for Sexual Health and HIV (BASHH), and reference lists of identified publications, are also searched. Similar search strategies have been used in the development of other national guidelines. Selected key publications are appraised using standard methodological checklists similar to those used by the National Institute for Health and Care Excellence (NICE). All papers are graded according to the Grades of Recommendations Assessment, Development and Evaluation (GRADE) system. Recommendations are graded as in the table on the inside front cover of this document using a scheme similar to that adopted by the RCOG and other guideline development organisations. The clinical recommendations within this Guidance are based on evidence whenever possible. Summary evidence tables are available on request from the CEU. The process for the development of CEU guidance is detailed on the FSRH website (www.fsrh.org). The methods used in the development of this guidance have been accredited by NHS Evidence.

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APPENDIX 2: DEFINITIONS OF UK MEDICAL ELIGIBILITY CRITERIA FOR CONTRACEPTIVE USE (UKMEC)

UKMEC Category	Definition of Category
1	A condition for which there is no restriction for the use of the contraceptive method.
2	A condition where the advantages of using the method generally outweigh the theoretical or proven risks.
3	A condition where the theoretical or proven risks generally outweigh the advantages of using the method. The provision of a method requires expert clinical judgement and/or referral to a specialist contraceptive provider, since use of the method is not usually recommended unless other more appropriate methods are not available or not acceptable.
4	A condition which represents an unacceptable health risk if the contraceptive method is used.
A	There is no medical reason to deny sterilisation to a person with this condition.
C	The procedure is normally conducted in a routine setting, but with extra preparation, precautions and counselling.
D	The procedure is delayed until the condition is evaluated, treated and/or changes. Alternative temporary methods of contraception should be provided.
S	The procedure should be undertaken in a setting with an experienced surgeon and staff, equipment needed to provide general anaesthesia, and other back-up medical support. For these conditions, the capacity to decide on the most appropriate procedure and anaesthesia method is also needed. Alternative temporary methods of contraception should be provided, if referral is required or there is otherwise any delay.
Initiation (I)	Starting a method of contraception by a woman with a specific medical condition.
Continuation (C)	Continuing with the method already being used by a woman who develops a new medical condition.

UKMEC CATEGORIES RELATING TO CURRENT CARDIAC CONDITIONS

	CHC	POP		IMP		DMPA/ NET-EN	LNG-IUS		Cu-IUD	Condoms	Diaphragm	Sterilisation
		I	C	I	C		I	C				
Current ischaemic heart disease	4	2	3	2	3	3	2	3	1	1	1	D
History of ischaemic heart disease	4	2	3	2	3	3	2	3	1	1	1	C
Uncomplicated valvular or congenital heart disease	2	1		1		1	1		1	1	1	C
Complicated valvular or congenital heart disease (e.g. with pulmonary hypertension)	4	1		1		1	2		2	1	2	S

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UKMEC CATEGORIES FOR ADDITIONAL CONSIDERATIONS/RISK FACTORS

	CHC	POP	IMP	DMPA/ NET-EN	LNG-IUS	Cu-IUD	Barrier methods
History of VTE	4	2	2	2	2	1	1
Current VTE (on anticoagulant)	4	2	2	2	2	1	1
Known thrombogenic mutation	4	2	2	2	2	1	1
Family history of VTE (first-degree relative) <45 years or ≥45 years	 3 2	 1 1	 1 1	 1 1	 1 1	 1 1	 1 1
Major surgery (operations of >30 minutes) with prolonged immobilisation	4	2	2	2	2	1	1
Major surgery without prolonged immobilisation	2	1	1	1	1	1	1
Minor surgery (<30 minutes) without immobilisation	1	1	1	1	1	1	1
Immobilisation (unrelated to surgery) (e.g. wheelchair use, debilitating illness)	3	1	1	1	1	1	1
Multiple risk factors for cardiovascular disease (such as old age, smoking, diabetes, hypertension	3/4	2	2	3	2	1	1
Known hyperlipidaemia	2/3	2	2	2	2	1	1

CHC, combined hormonal contraception; Cu-IUD, copper intrauterine device; DMPA, depot medroxyprogesterone acetate; IMP, progestogen-only implant; LNG-IUS, levonorgestrel intrauterine system; NET-EN, norethisterone enantate; POP, progestogen-only pill; VTE, venous thromboembolism.

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APPENDIX 3: METHODS OF CONTRACEPTION AVAILABLE IN THE UK

Method	Primary mechanism of action	Hormones used and dose	How to use	Efficacy*	Advantages	Disadvantages
COC	Inhibition of ovulation	Estrogens • Ethinylestradiol 20–35 µg • Estradiol valerate 1–3 mg varies between 1 and 3 mg during 28 pack • Estradiol hemihydrate 1.5 mg • Mestranol 50 µg Progestogens • Levonorgestrel 50–150 µg • Norethisterone 500 µg–1mg • Norgestimate 250 µg • Gestodene 50–100 µg • Desogestrel 150 µg • Cyproterone acetate 2 mg • Drospirenone 3 mg • Nomegestrol 2.5 mg • Dienogest 2–3 mg	Standard regimen Oral pill taken daily for 21 days followed by 7-day pill-free interval. Other regimens exist	Up to 99% effective if used consistently and correctly (perfect use) With typical use around 9% failure in first year of use	Improvement in HMB, acne and hirsutism Reduced risk of ovarian and endometrial cancer	Risk of thrombosis Small increased risk of cervical cancer and possible small increased risk of breast cancer Restrictions apply if history of migraine Efficacy is more user dependent than LARC methods and sterilisation Hormonal side effects
CTP		Ethinylestradiol 33.9 µg and Norelgestromin 203 µg (over 24 hours)	New patch applied every 7 days for 21 days followed by 7-day patch-free interval			
CVR		Ethinylestradiol 15 µg and Etonogestrel 120 µg (over 24 hours)	Ring inserted for 21 days followed by 7-day ring-free interval			
Desogestrel POP	Inhibition of ovulation	Desogestrel 75 µg	Pill taken every day of the week	Up to 99% effective if used consistently and correctly (perfect use) With typical use around 9% of women will experience a pregnancy in the first year of use	Current evidence suggests no increased risk of thrombosis, stroke or MI associated with use	Efficacy is more user dependent than LARC methods and sterilisation Changes to bleeding patterns common – may stop, be more frequent or irregular Hormonal side effects
Traditional POP	Changes to cervical mucus	Norethisterone 350 µg Levonorgestrel 30 µg				
Progestogen-only implant	Inhibition of ovulation	Etonogestrel 68 mg	Implant inserted every 3 years	Highly effective method >99% effective with perfect or typical use	Evidence suggests no increased risk of thrombosis, stroke or MI associated with use	Altered bleeding patterns common – may stop, be more frequent or irregular

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APPENDIX 3: METHODS OF CONTRACEPTION AVAILABLE IN THE UK

Method	Primary mechanism of action	Hormones used and dose	How to use	Efficacy*	Advantages	Disadvantages
DMPA IM SC	Inhibition of ovulation	 Depot medroxy-progesterone acetate 150 mg Depot medroxy-progesterone acetate 104 mg	Injection given every 3 months	>99% effective with (perfect use) With typical use around 6% of women will experience a pregnancy in the first year of use	Evidence suggests no increased risk of stroke or MI associated with use Efficacy not affected by enzyme-inducing drugs May be beneficial in the management of HMB and endometriosis Amenorrhoea expected in 70% of women by 1 year SC injection may be associated with lower risk of injection site haematoma than IM	Evidence of weight gain with use, particularly in young women with BMI >30 kg/m^2 Altered bleeding patterns common Bone mineral density loss, resolves after discontinuation and no increased risk of fracture There can be a delay of up to 1 year in the return of fertility after discontinuation of DMPA Hormonal side effects
LNG-IUS	Changes to endometrium and cervical mucus	Levonorgestrel 52 mg (Mirena©) Levonorgestrel 13.5 mg (Jaydess©)	Licensed for contraceptive use for up to 5 years Licensed for contraceptive use for up to 3 years	Highly effective method >99% effective with perfect or typical use	Evidence suggests no increased risk of thrombosis, stroke or MI associated with use Mirena can be used in the management of HMB Efficacy not affected by enzyme-inducing drugs	Irregular bleeding common in first 6 months; thereafter amenorrhoea or spotting is common in Mirena users but less likely with Jaydess Hormonal side effects but often resolve after first 3–6 months
Cu-IUD	Copper toxic to sperm and ovum	Non-hormonal	Different devices licensed for 5–10 years of use. Can also be used as EC	Highly effective method >99% effective with perfect or typical use	Non-hormonal No associated increased risk of thrombosis, stroke or MI Efficacy not affected by enzyme-inducing drugs	Spotting, light bleeding, heavier or prolonged bleeding are common in the first 3–6 months of use
Condoms	Barrier to ejaculate and pre-ejaculate	Non-hormonal	Male condoms are rolled down an erect penis	Male condoms are up to 98% effective with perfect use (consistently and correctly for every incident) Around 18% of women will experience a pregnancy in the first year of use with typical use	Non-hormonal No associated increased risk of thrombosis, stroke or MI Efficacy not affected by enzyme-inducing drugs Protect against STIs	Ill-fitting male condoms can cause condoms to slip off or split With typical use, efficacy is less than other contraceptive methods

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APPENDIX 3: METHODS OF CONTRACEPTION AVAILABLE IN THE UK

Method	Primary mechanism of action	Hormones used and dose	How to use	Efficacy*	Advantages	Disadvantages
Condoms (continued)			Female condoms are inserted into the vagina	Female condoms are up to 95% effective with perfect use (consistently and correctly for every incident) Around 21% of women will experience a pregnancy in the first year of use with typical use		
Male sterilisation (vasectomy)	The vas deferens are cut, sealed or tied	Non-hormonal	Surgical procedure- usually performed under local anaesthetic	Highly effective method >99% effective with perfect or typical use	Not easily reversible	Effect not immediate Short-term discomfort or pain, occasionally chronic testicular pain
Female sterilisation (tubal occlusion)	Fallopian tubes are cut, sealed or blocked	Non-hormonal	Performed laparoscopic-ally under general anaesthetic or hysteroscopi-cally without anaesthetic	>99% effective with perfect or typical use	Not easily reversible No change to menstruation	May experience discomfort or pain for a short time after sterilisation Not easily reversible (hysteroscopic sterilisation completely irreversible) 1 in 200 lifetime failure rate which is less effective than some LARC methods and vasectomy If previously using hormonal methods, may experience heavier bleeding when periods return Effect of hysteroscopic sterilisation not immediate, imaging required to confirm tubal occlusion
Fertility awareness methods (natural family planning)	Using signs and symptoms to identify the fertile period allowing individuals to plan or avoid pregnancy	Non-hormonal	Observe and record fertility indicators throughout the menstrual cycle (e.g. body temperature, cervical secretions, length of menstrual cycle)	LAM is 98% effective Other methods are 76–94% effective with typical use	Does not involve any physical devices or hormones No physical side effects Acceptable to all faiths and cultures	LAM reliable only if fully breastfeeding and <6 months postpartum Additional precautions during fertile period May take 3–6 cycles to learn

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APPENDIX 3: METHODS OF CONTRACEPTION AVAILABLE IN THE UK

Method	Primary mechanism of action	Hormones used and dose	How to use	Efficacy*	Advantages	Disadvantages
Oral EC	Used following UPSI to prevent pregnancy	Levonorgestrel 1.5 mg or Ulipristal acetate 30 mg	LNG licensed up to 72 hours after UPSI (unlicensed use up to 96 hours) UPA licensed for use up to 120 hours after UPSI	Both methods are effective if taken prior to ovulation. Less effective once ovulation has occurred		Efficacy of both methods affected by enzyme-inducing drugs. Double dose of LNG can be administered

*Efficacy figures for CHC, POP, implant, injectable, intrauterine methods and condoms adapted from data produced by Trussell.[82]

BMI, body mass index; CHC, combined hormonal contraception; COC, combined oral contraceptive pill; CTP, combined transdermal patch; Cu-IUD, copper intrauterine device; CVR, combined cervical ring; DMPA, depot medroxyprogesterone acetate; EC, emergency contraception; HMB, heavy menstrual bleeding; IM, intramuscular; LAM, lactational amenorrhoea; LARC, long-acting reversible contraception; LNG, levonorgestrel; LNG-IUS, levonorgestrel intrauterine system; POP, progestogen-only pill; SC, subcutaneous; STI, sexually transmitted infection; UPA, ulipristal acetate; UPSI, unprotected sexual intercourse.

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APPENDIX 4: RISK CONFERRED BY PREGNANCY IN WOMEN WITH CARDIAC DISEASE*

Risk class	Risk pregnancy may infer by medical condition
I	No detectable increased risk of maternal mortality and no/mild increase in morbidity.
II	Small increased risk of maternal mortality or moderate increase in morbidity.
III	Significantly increased risk of material mortality or severe morbidity. Expert counselling is required. If pregnancy is decided upon, intensive specialist cardiac and obstetric monitoring needed through pregnancy, childbirth and the puerperium.
IV	Extremely high risk of maternal mortality or severe morbidity; pregnancy contraindicated. If pregnancy occurs termination should be discussed. If pregnancy continues, care as for Class III.

Conditions in which the risk associated with pregnancy is classed as I	
1	Uncomplicated, small or mild: pulmonary stenosis; patent ductus arteriosus; mitral valve prolapse
2	Successfully repaired simple lesions (atrial or ventricular septal defect, patent ductus arteriosus, anomalous pulmonary venous drainage)
3	Atrial or ventricular ectopic beats, isolated
Conditions in which the risk associated with pregnancy is classed as II	
1	Unoperated arterial or ventricular septal defect
2	Repaired teralogy of Fallot
3	Most arrhythmias
Conditions in which the risk associated with pregnancy is classed as II–III (depending on the individual)	
1	Mild left ventricular impairment
2	Hypertrophic cardiomyopathy
3	Native or tissue valvular disease not considered Class I or IV
4	Marfan syndrome without aortic dilation. Aorta <45 mm in aortic disease associated with bicuspid aortic valve
5	Repaired coarctation
Conditions in which the risk associated with pregnancy is classed as III	
1	Mechanical valve
2	Systemic right ventricle
3	Fontan circulation
4	Cyanotic heart disease (unrepaired)
5	Other complex congenital heart disease
6	Aortic dilation 40–45 mm in Marfan syndrome/aortic dilation 45–50 mm in aortic disease associated with bicuspid aortic valve
Conditions in which the risk associated with pregnancy is classed as IV	
1	Pulmonary arterial hypertension of any cause
2	Severe systemic ventricular dysfunction (LVEF <30% NYHA III IV)
3	Previous peripartum cardiomyopathy with any residual impairment of left ventricular function
4	Severe mitral stenosis, severe symptomatic aortic stenosis
5	Marfan syndrome with aorta dilated >45 mm, aortic dilation >50 mm in aortic disease associated with bicuspid aortic valve
6	Native severe coarctation

*Sources: Thorne *et al.*[126] and European Society of Cardiology *ESC Guidelines on the Management of Cardiovascular Diseases During Pregnancy*[18] adapted with permission of Oxford University Press (UK) © European Society of Cardiology (www.escardio.org/guidelines).
LVEF, left ventricular ejection fraction; NYHA, New York Heart Association.

APPENDIX 5: INTERACTIONS BETWEEN CARDIAC DRUGS AND CONTRACEPTION

Class of drug	Effect on contraceptive efficacy	Other known effect/interaction	Other
Antihypertensive drugs (excluding bosentan)	None expected	Hypotensive effect of antihypertensive drugs may be antagonised by combined hormonal contraception; therefore the effects may need to be monitored	
Bosentan	Yes – produces a modest reduction in ethinylestradiol and progestogen[96,98,127] Advise switching to an alternative method unaffected by enzyme inducers (e.g. progestogen-only injectable or intrauterine method)[96]		
Diuretics	None expected	Theoretical risk of hyperkalaemia when potassium-sparing diuretics and aldosterone antagonists are used in conjunction with drospirenone Estrogen may antagonise the diuretic effects	
Immunosuppressants	None expected	Plasma levels of tacrolimus are possibly increased by ethinylestradiol, norethisterone enantate and gestodene[96,128] Tacrolimus is an enzyme inhibitor and theoretically may inhibit the metabolism of estrogens and progestogen leading to increased levels. The clinical significance of this is unknown but the increase is likely to be small[96] Plasma concentrations of ciclopsorin may be increased by estrogen or progestogen[129]	Effective contraception required before, during and after treatment with certain immunosuppressants due to concerns about teratogenic effect It has been postulated that inflammatory changes in the endometrium as a result of a Cu-IUD may be attenuated by immunosuppressant or anti-inflammatory drugs. Although the SPC for azathioprine contains cautionary advice,[130] there is no robust evidence to support a reduced effect[131]

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APPENDIX 5: INTERACTIONS BETWEEN CARDIAC DRUGS AND CONTRACEPTION

Class of drug	Effect on contraceptive efficacy	Other known effect/interaction	Other
Lipid-lowering drugs Statins	None expected	Minor to modest increase in estrogen and progestogen with atorvastatin and rosuvastatin levels – clinical significance unknown	
Colesevelam			Advised that other drugs should be taken at least 4 hours before or after colesevelam to reduce possible interference with absorption
Antiarrhythmic drugs	None expected	–	
Antidiabetic drugs	None expected	Estrogens and progestogens antagonise the hypoglycaemic effect	–

Cu-IUD, copper intrauterine device; SPC, Summary of Product Characteristics.

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APPENDIX 6: SEXUAL ACTIVITY AND CARDIOVASCULAR DISEASE*

Reasonable to initiate or resume sexual activity	Stabilisation of condition advised before resuming/initiating sexual activity
Patients who can exercise ≥3–5 METs without angina, excessive dyspnoea, ischaemic ST-segment changes, cyanosis, hypotension or arrhythmia (except patients with incomplete coronary revascularisation warrant further investigation before resuming sexual activity)	Patients with unstable, decompensated, and/or severe symptomatic CVD
Patients with no or mild angina	Patients with unstable or refractory angina
Patients ≥1 week after uncomplicated MI if they are without cardiac symptoms during mild-moderate physical activity	Patients with decompensated or advanced (NYHA Class III or IV) heart failure
Patients who have undergone complete coronary revascularisation and may be resumed: • Several days after percutaneous coronary intervention if the vascular access site it without complications • 6–8 weeks after the procedure provided the sternotomy is well healed	Severe or significantly symptomatic valvular disease
Patients who have undergone non-coronary heart surgery sexual activity may be resumed 6–8 weeks after the procedure provided the sternotomy is well healed	Patients with atrial fibrillation and poorly controlled ventricular rate, uncontrolled or symptomatic supraventricular arrhythmias and spontaneous or exercise-induced ventricular tachycardia
Patients with compensated and/or mild (NYHA Class I or II) heart failure	Patients with an ICD who have received multiple shocks until the causative arrhythmia is stabilised and optimally controlled
Patients with mild or moderate valvular heart disease and no or mild symptoms	Patients with hypertrophic cardiomyopathy who are severely symptomatic until their condition is stabilised
Patients with normally functioning prosthetic valves, successfully repaired valves and successful transcatheter valve interventions	
Patients with atrial fibrillation or atrial flutter and well-controlled ventricular rate	
Patients with pacemakers	
Patients with an ICD used for secondary prevention in whom moderate physical activity (≥3–5 METs) does not precipitate ventricular tachycardia or fibrillation and who do not receive frequent multiple appropriate shocks	
Most patients with congenital heart disease who do not have decompensated or advanced heart failure, severe and/or significantly symptomatic valvular disease, or uncontrolled arrhythmias	
Most patients with hypertrophic cardiomyopathy	

*Source: American Heart Association, Inc.[122]
CVD, cardiovascular disease; ICD, implantable cardioverter-defibrillator; MET, metabolic equivalent; MI, myocardial infarction; NYHA, New York Heart Association.

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Questions for Continuing Professional Development

The following questions have been developed for continuing professional development (CPD).

The answers to the questions and information on claiming CPD points can be found in the 'members-only section' of the FSRH website (www.fsrh.org), which is accessible to all Diplomates, Members, Associate Members and Fellows of the FSRH.

1 Which of the following is an indicator of a cardiac condition being low risk:

a. A woman having follow-up every 2 years
b. A woman having follow-up every year
c. A woman with high oxygen saturation
d. A woman taking oral cardiac medications only

2 For which of the following conditions would you consider a hospital setting for the insertion of an intrauterine device?

a. Fontan's circulation
b. Uncomplicated patent ductus arteriosus
c. Repaired ventricular septal defect
d. Uncomplicated pulmonary stenosis

3 For which of the following conditions is pregnancy considered low risk?

a. Fontan's circulation
b. Ventricular ectopic beat
c. Pulmonary hypertension
d. History of peripartum cardiomyopathy

4 Peripartum cardiomyopathy usually starts any time from:

a. 3 months of pregnancy until 1 month after birth
b. 5 months of pregnancy until 3 months after birth
c. 6 months of pregnancy until 4 months after birth
d. The last month of pregnancy until 6 months after birth

5 As a general rule how long should pregnancy be avoided after a solid organ transplant procedure?

a. 3 months
b. 6 months
c. 9 months
d. 12 months

6 When routinely inserting or removing an IUD in a woman at risk of infective endocarditis which of the following antibiotic regimens is correct?

a. Antibiotics are not routinely required
b. A course of amoxicillin should be taken for 1 week before the procedure
c. A course of amoxicillin should be taken for 1 week after the procedure
d. Admission to hospital is required for administration of intravenous antibiotics

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7 The increased risk of VTE with use of CHC compared to non-users is approximately:

a. Double
b. Quadruple
c. The same
d. Half

8 Regarding use of progestogen-only contraception and VTE risk which of the following is correct?

a. A causal link has been demonstrated
b. A causal link has not been demonstrated
c. Progestogen-only contraception has been shown to double the risk of VTE
d. Progestogen-only contraception has been shown to halve the risk of VTE

9 Which one of the following antihypertensives has been shown to reduce the effect of estrogen and progestogen?

a. Amlodipine
b. Bosentan
c. Captopril
d. Propranolol

10 Which of the following contraceptive methods would be associated with a UKMEC Category 4 in a woman who had a myocardial infarction 6 months ago?

a. The IUS
b. The progestogen-only injectable
c. The subdermal implant
d. The contraceptive vaginal ring

What learning needs did this guidance address and how will it change your practice? (Please write below)

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Auditable Outcomes for Contraceptive Choices for Women with Cardiac Disease

The following auditable outcomes have been suggested by the FSRH Clinical Standards Committee.

Auditable Outcomes

1 What proportion of women with a history of congenital cardiac disease, at transition from paediatric to adult services, hold information provided by their cardiologist that may be relevant to future care including risks associated with contraception and pregnancy?

2 What proportion of women with cardiac disease who decide to use intrauterine contraception have documented evidence of involvement from a cardiologist?

3 What proportion of women with cardiac disease have documented evidence that they and their partner have been given the opportunity to discuss sex or sexual function and to have any concerns addressed?

4 What proportion of women with cardiac disease have documented evidence of having undergone a discussion about strategies for reducing the risk of unintended pregnancy? (see list of examples in Box 3 on page 9)

5 What proportion of women with cardiac disease who wish to conceive have documented evidence that they have been advised to continue contraception until they have had specialist preconception advice?

COMMENTS AND FEEDBACK ON PUBLISHED GUIDANCE

All comments on published guidance can be sent directly to the Clinical Effectiveness Unit (CEU) at **ceu.members@ggc.scot.nhs.uk.**

The CEU is unable to respond individually to all feedback. However, the CEU will review all comments and provide an anonymised summary of comments and responses, which are reviewed by the Clinical Effectiveness Committee and any necessary amendments made.