Worcestershire Acute Hospitals NHS Trust

Recurrent Miscarriage Guideline
≥3 Miscarriages

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Key Amendments

Date	Amendment	Approved by
26th January 2019	Documents extended for 3 years	Mr Hughes
14th December 2020	Documents approved for 3 years	Miss Blackwell
22nd July 2022	Appendix 2 added – progesterone use	Miss Blackwell
14th March 2025	Document updated – as per RCOG GTG update Appendix 5 added – Miscarriage investigations and follow-up flowchart	Miss Blackwell

Glossary

GTG	Green Top Guideline
RMC	Recurrent Miscarriage
RPL	Recurrent Pregnancy Loss
MC	Miscarriage
FBC	Full Blood Count
TSH	Thyroid stimulating hormone
TPO	Thyroid peroxidase
BMI	Body mass index
VTE	Venous thromboembolism
TVUSS	Transvaginal ultrasound scan
APS	Antiphospholipid syndrome
- LA	Lupus anticoagulant
- ACA	Anticardiolipin antibody
- B2GP1	Beta 2 Glucoprotein 1
DM	Diabetes mellitus
BWH	Birmingham Women's Hospital
EPAU	Early Pregnancy Assessment Unit
IVF	In Vitro Fertilisation
ESHRE	European Society of Human Reproduction and Embryology
PCOS	Polycystic ovarian syndrome
FAI	Free androgen Index
LMWH	Low molecular weight heparin
SCH	Subclinical hypothyroidism

Graded approach to investigating miscarriages:
1 MC→ patient information leaflet and support
2 MC→ as for 1 and offer (only): FBC & thyroid screen (TSH and TPO antibodies)
3 MCs→ RMC as below
See Miscarriage flowchart: Appendix 5

Management of patients **with recurrent miscarriages (≥3)** or suspected/known Antiphospholipid Syndrome (APS).

Lifestyle advice:
- Maintain BMI 19-25
- Smoking cessation
- Limit alcohol consumption
- Limit caffeine to <200mg/day
- Anxiety management, stress

See in specific RMC clinic - *referral on Bluespier*

History:
- Gestation
- Obs and Gynae risk factors
- PMH: VTE, APS
- FH: VTE
- Previous treatment

Information to patient:
- Rarely find a cause
- Not all causes have a treatment
- Lifestyle changes
- Progesterone if spotting & previous MC: *PRISM*
- No benefit of routine Progesterone: *PROMISE*
- No benefit of LMWH/aspirin unless APS
- RCOG Patient leaflet & Cedar Tree counselling

Investigations:
- Antiphospolipid antibodies: lupus anticoagulant
  - Anticardiolipin antibodies (IgM and IgG)
  - Anti-**B**2GP1 (IgM and IgG)
- FBC and HbA1c (Prolactin: if clinical suspicion)
- TSH & TPO antibodies (if abnormal check free T4)
- Pelvic USS (further imaging as needed)
- Send products for karyotyping if ≥3 miscarriage (if abnormal check parents)

APS antibodies positive:
- Ensure taken >6 weeks after miscarriage
- Repeat 12 weeks later to confirm

2x Positive results = APS
- Treatment: Aspirin and LMWH until at least 34wks
- From Positive pregnancy test to decrease the risk of miscarriage (by 54%)

Optimise health, BMI, smoking, DM & thyroid control, Folic acid, vitamin D, Rubella status.

Abnormal karyotype:
- Parental karyotyping
- Refer to BWH genetics team

Abnormal TVUSS:
- Hysteroscopy or laparoscopy
- Renal USS
- Treat as necessary

Unexplained / All patients:
- Lifestyle advice, support & reassurance
- Self-referral to EPAU
- Serial early USS
- Progesterone (if indicated, accepted)
  - 400mg BD pv/pr from spotting until 16weeks
  - *(off-label use of Cyclogest)*
- Counselling: Cedar Tree 01905 616166 cedartreeworcs@gmail.com

Recurrent Miscarriage (RMC) Guideline

Updated as per the New RCOG Green-top Guidance No. 17 June 2023.
TOG 2022 and SIP No.70

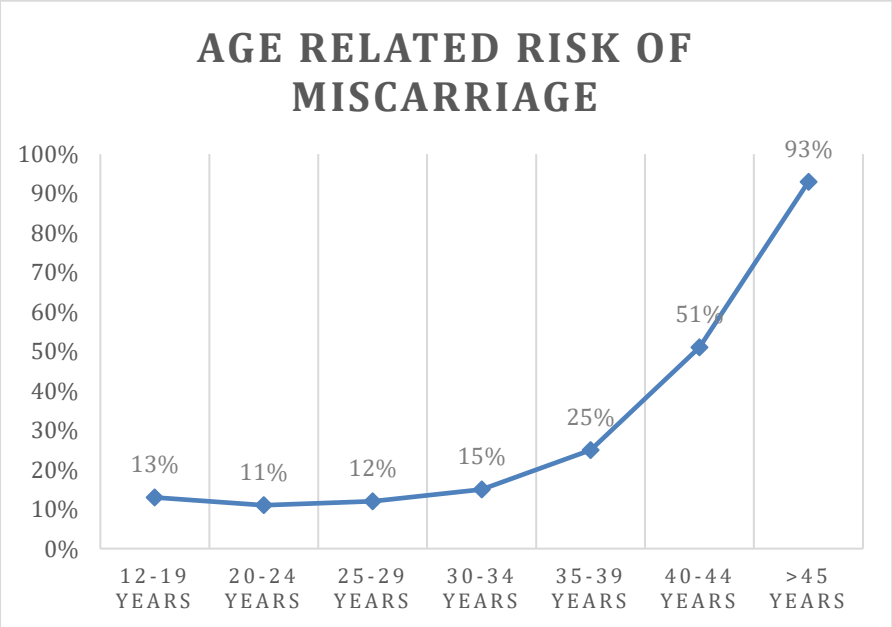
A miscarriage (MC) is the spontaneous loss of a pregnancy before the fetus reaches viability at 24 weeks. Chromosomal anomaly of the pregnancy is the commonest cause of sporadic and recurrent miscarriage (RMC). Miscarriage of euploid pregnancy, is associated with an increased risk of subsequent MC. 1 in 8 recognised pregnancies end in pregnancy loss.

A sporadic miscarriage tends to occur in the first trimester, with 50% due to fetal chromosomal anomalies; trisomy (51.9%), polyploidy (18.8%), monosomy (15.2%), structural anomalies (6.5%) and other (7.6%). The rate increases with age.
Recurrent miscarriage (RMC) or recurrent pregnancy loss (RPL) is the loss of 3 or more first trimester pregnancies. It affects 0.7% of couples.

The New RCOG guideline has kept the definition of 3 miscarriages, but no longer states these need to be consecutive or with the same partner. ESHRE 2017, however uses 2 or more, which would increase the incidence to 1.9%. Couples should however be investigated after two, if it is felt the miscarriages are pathological in nature. The Lancet series of three articles dedicated to miscarriage, suggesting a graded model of care, as regards the investigations and management of patients with miscarriages. [Appendix 3]. This varying advice may lead to confusion and differing views of patients and clinicians.

Risk factors for Miscarriage:

1. **Age.**
   a) Maternal age: the greatest determinant of the incidence of RMC is age. This is due to the decline in the number and quality of the remaining oocytes; resulting in increased aneuploidy.
   b) Paternal age: if ≥40 years, however less pronounced effect.

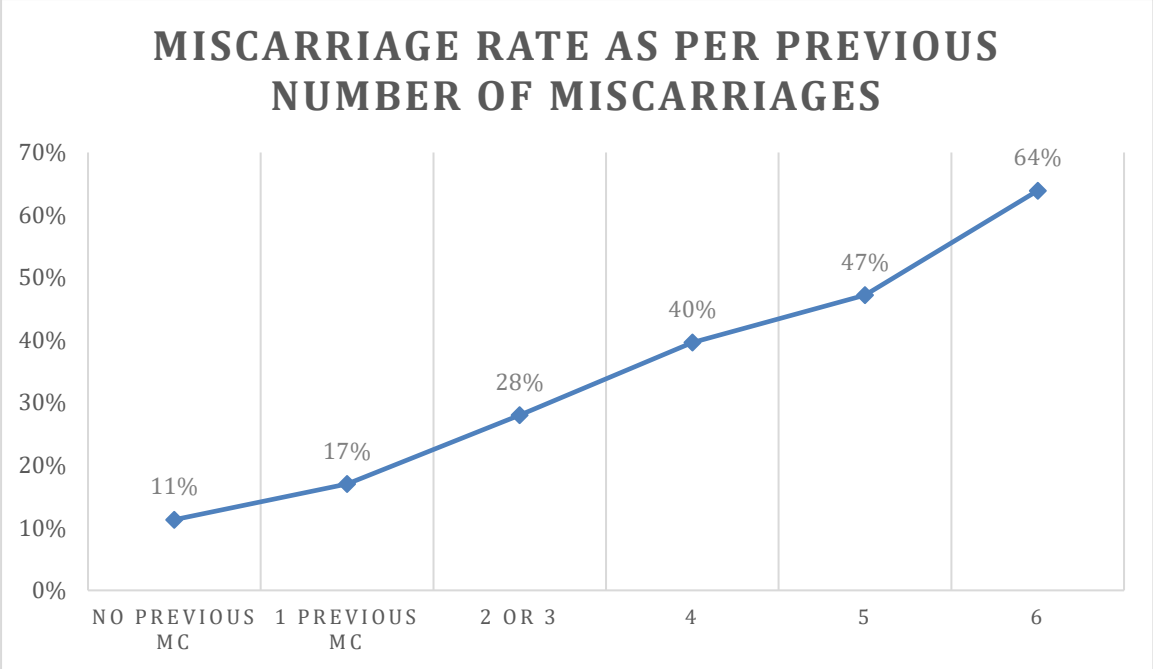


(RCOG GTG 17, BMJ 2000)

2. Ethnicity.

There is an increased risk of sporadic miscarriage in Black African and Black Caribbean women. There was no link found with consanguinity.

3. Previous number of miscarriages.



The risk of future miscarriage increases with each successive loss. This is similar for those with a previous live birth.

4. Lifestyle.

a) Smoking and caffeine consumption: associated with sporadic MC.
b) Excessive alcohol consumption of >10units/week - increased spontaneous MC: toxic to embryos and fetus.
c) BMI <19 or >25: strong risk factor for both sporadic and recurrent miscarriage (especially >30). It is also linked to obstetric complications in the pregnancy.
d) Excessive exercise can have a negative impact.
e) Stress: limited evidence, night shifts potentially linked.

5. Antiphospholipid Syndrome (APS) – acquired thrombophilia.

APS causes inhibition of trophoblastic function and differentiation, activation of complement pathways at the maternal–fetal interface resulting in a local inflammatory response, and thrombosis of the uteroplacental vasculature in later pregnancy.

APS is defined as:

a) Antiphospholipid antibodies: (present in 15% of women with recurrent miscarriage, verses 2% of the general population)
    - lupus anticoagulant (LA) [strongest association]
    - anticardiolipin antibodies (ACA IgG & IgM)
    - anti-ß$_2$ glycoprotein-I antibodies (IgG & IgM) [weakest association]

plus:

b) Vascular thrombosis, **or**
c) An adverse pregnancy outcome:

- ≥3 consecutive miscarriages at <10 weeks gestation
- ≥1 morphologically normal fetus loss >10 weeks gestation
- ≥1 preterm birth at <34 weeks due to placental disease

6. Inherited thrombophilia

This causes a hypercoaguable state that leads to thrombosis of the uteroplacental circulation. Only screen as part of a research trial or if a strong family history exists with second trimester miscarriages, not routinely, as only a weak association with RMC.

a) Factor V Leiden mutation (activated protein C deficiency): associated with first, but especially second trimester RMC.
b) Prothrombin gene mutation: is associated with recurrent miscarriage.
c) Protein S deficiency: associated with 2nd trimester miscarriage:

➔ **However, no treatment for these has be found to be beneficial at reducing recurrent or 2nd trimester miscarriage.**

d) Methylenetetrahydrofolate mutation (MTHFR), protein C deficiencies and antithrombin deficiencies: mixed evidence of an association, so not recommended.

7. Genetic factors.

a) Parental chromosomal rearrangement: In 2-5% of couples with recurrent miscarriage. If one partner carries a balanced structural chromosomal anomaly (balanced reciprocal or Robertsonian translocation) they still have an 83% chance of having a healthy child. One study showed a translocation is present in 2.2% of parents after one miscarriage, 4.8% after two miscarriages, and 5.7% after three miscarriages.
b) The risk of subsequent MC is dependent on the type of rearrangement: reciprocal translocations 54%, inversions 49%, Robertsonian translocations 34% and other types of chromosomal anomalies 27%.
c) The incidence of aneuploidy in RMC is 40%, implying that non-genetic factors may play a more important role in recurrent miscarriage.
d) Fetal chromosomal anomalies may be the commonest cause of both sporadic and RMC.
e) Studies have shown: as the number of euploid MC; the increased risk of further MC. Possibly due to maternal pathology rather than sporadic aneuploidy. Like-wise, aneuploidy improves the chance of a good outcome in the next pregnancy. (age adjusted).
f) The STAR (Single Embryo Transfer of Euploid Embryo) study: no benefit in pregnancy outcome with the use of IVF in combination with pre-implantation genetic testing for aneuploidy screening (PGT-A).

8. Anatomical factors.

a) Congenital uterine malformations - septate and bicornuate uteri: increased risk of 1st trimester miscarriage
    - Present in 5.5% of unselected women, 8% in infertile women, 13.3% in women with recurrent miscarriages, 24.5% in women with infertility and recurrent miscarriages.
b) Not associated with sporadic 1st trimester miscarriages: arcuate, didelphys, unicornuate uteri
    - ESHRE has reclassified arcuate as a normal variant, with no clinical implications.
c) Associated with 2nd trimester miscarriages: arcuate, septate, bicornuate uteri

b) Myomas: overall no increased risk of miscarriage, no more common in RMC patients than general population.

a) submucosal: higher risk of 2nd trimester miscarriages, with a significant reduction (21.7%) following resection.
b) intramural/subserosal myomas: varied data

c) Polyps: minimal data, so manage as general population

d) Intrauterine adhesions: lack of data to confirm. Potential mechanism: constriction of cavity, reduced normal endometrial tissue for implantation and placental development, reduced vascularization of the remaining endometrium.
   a) The incidence of adhesions increases with number of miscarriages and surgical managements to treat these.
   b) Intrauterine adhesions and endometrial thickness <5 mm: 50% miscarriage rate versus >5 mm (8.3%).

e) Cervical weakness: one of the main causes of 2nd trimester miscarriage. Cannot determine in non-pregnant woman.
f) Hydrosalpinx: presence may increase risk of pregnancy loss and treatment can reduce this risk in patients undergoing IVF.

9. Endocrine factors.

Well controlled diabetes and treated thyroid dysfunction: not associated with RMC.
Diabetes:

a) Diabetes mellitus: a raised HbA1c in the 1st trimester is associated with an increased risk of miscarriage and fetal malformation.
   - NICE guidance 2020, recommend HbA1c <48mmol/mol (6.5%) prior to conception. And strongly advise against pregnancy when HbA1c >86mmol/mol (10%) due to increased risks.

Thyroid:

b) Subclinical hypothyroidism (TSH>2.5mIU/l): may be associated with increased risk
c) Thyroid autoantibodies: may also be associated with recurrent miscarriage.
d) Hyperthyroidism: no known link with RMC

e) PCOS: may be associated, but unclear how. Potentially related to insulin resistance, hyperinsulinaemia, hyperandrogenaemia. No evidence it is linked to raised LH or testosterone levels.
   - RMC are associated with insulin resistance, abnormal GTT (glucose tolerance test) and elevated free androgen index (FAI).
f) Prolactin - A small study showed benefit of treatment of hyperprolactinaemia with bromocriptine, on live birth rate (85.75 vs 52.4%).
g) Do not test for ovarian reserve, luteal phase insufficiency (midluteal progesterone, luteinizing hormone (LH) or androgens; as there is no evidence of link or beneficial treatment.

10. Immune factors – do not offer

a) Cytokines (Th1/Th2 imbalance) (T-helper cells): further research required.
b) Human leucocyte antigen (HLA): no constant link
c) Increased peripheral natural killer cells (NK cells): significance debatable, and do not appear to reflect the levels in the endometrium or predict subsequent miscarriage.
   - Increased uterine NK cell density: associated with recurrent miscarriage, but prognostic value and treatment remains unconfirmed
d) ANA (antinuclear antibodies): may have an association with RMC, but there is no evidence based proven treatment

11. Infective agents.

a) Bacteraemia or viraemia: sporadic, not recurrent miscarriage, therefore TORCH (*toxoplasmosis, rubella, cytomegalovirus, herpes simplex and HIV*) screening should not be done.
b) Bacterial vaginosis in the 1st trimester is a risk for 2nd trimester miscarriage and preterm labour and should be treated, but is not associated with recurrent miscarriage.
c) Chronic endometritis: diagnostic criteria remain controversial.

12. Male factors.

a) Reduced semen parameters: not associated in all cases
b) Anti-sperm antibodies: inconsistent data
c) Sperm DNA fragmentation: high levels may be associated with RMC. The main cause of DNA damage is oxidative stress and this seems to be exacerbated by smoking, obesity and excessive exercise. Investigation not available on the NHS, and should not be routinely offered outside of research context.
    - Antioxidant supplementation may be beneficial.
d) Optimise lifestyle: smoking cessation, optimize weight, reduce pollutant exposure, treat infections/DM/varicoceles.

Investigations: for RMC (≥3 1st trimester) (or ≥1 2nd trimester MC)

1. Acquired thrombophilia - Antiphospholipid antibodies (LA, ACA [IgG and IgM], ß2GP1 [IgG and IgM])
    a) >6 weeks following a miscarriage.
    b) If 1st test positive → repeat in 12 weeks to confirm (may be transient positivity due to infection).
    c) Diagnostic if >40. If in doubt (ie 10-40) or patient conceives prior to repeat confirmatory testing – discuss with the Haematology team.
        a) *General advice from Haematology at WRH (confirm case by case as needed):*
            i. *negative if <20 (do not repeat),*
            ii. *repeat if >20*
            iii. *if pregnant prior to repeat: >20 - treat in pregnancy and confirm diagnosis postpartum.*
2. Inherited thrombophilia screen (only if 2nd trimester miscarriage):
    a) Do not routinely test, unless strong family history or as part of a research trial.
    b) Only if 2nd trimester: Factor V Leiden, prothrombin (factor II) gene mutation, protein S. >6 weeks postpartum, and in the absence of hormonal medication, still should be part of research trial.

3. Other routine investigations:
    a) TSH and thyroid peroxidase (TPO) antibodies (if abnormal, test for free T4)
    b) HbA1c and prolactin – if clinical suspicion (RCOG)

4. Pelvic USS: to exclude congenital uterine abnormalities.
    a) If unclear: [3D USS where available], Hysterosalpingogram (HSG), hysteroscopy or laparoscopy. Reserving MRI for complex cases.
    b) If a mullerian uterine malformation detected, for a renal USS.

5. Genetic: Pregnancy tissue on the 3rd and any future 1st trimester miscarriages (and all 2nd trimester losses) should be sent for cytogenetic analysis; for karyotyping.
    a) If an unbalanced structural chromosomal abnormality is found → perform parental peripheral blood karyotyping. *This will be recommended by the genetics*

depeartment on the results form if necessary. If abnormal, promptly refer to a clinical geneticist.

b) Where cytogenetic analysis is indicated, but unsuccessful or no pregnancy tissue available, parental karyotyping should be offered. **Regionally this is only available after the 5th miscarriage.**

c) Cytogenetic analysis of pregnancy tissue has been shown to provide a diagnosis in over 90% of couples.

Management:

The Lancet series recommended a graded approach to miscarriage. After 1 miscarriage: women should have their health needs evaluated, and given information and guidance to support future pregnancies. After a second miscarriage they should be seen in a nurse or midwife lead miscarriage clinic (*not presently feasible at WRH*), for initial investigations, extra support and early reassurance scans in future pregnancies. After three miscarriages, they should have a full series of evidence-based investigations and care as per the RCOG guidance.

RMC (≥3MC)

1) Refer couple to the recurrent miscarriage clinic.

a) Referral form on Bluespier: to be edited and sent (normally by nursing team in EPAU).

b) The couple should be seen together and given supportive care This alone has been shown to result in a better prognosis for future pregnancy, with a 75% success rate, compared with 51% miscarriage rate in next pregnancy for those who do not attend the clinic. However, this prognosis worsens with maternal age and each additional MC.

c) It is a challenging clinical scenario with associated psychological trauma. A full medical and obstetric history should be taken at the first appointment.

i) Should also not underestimate the emotional impact of looking after these patients on the staff: doctors, nurses, other health care professionals and secretarial support staff

d) Health care professionals should recognize that for the couple this is a significant life event.

e) Discuss possible causes, investigations and treatments, ensuring couples aware that unfortunately investigations rarely lead to treatment options, and some causes have little or no proven treatment. Give a time scale for investigation results and follow up for discussion of these. Only 36% of couples have an explained cause.

f) Lifestyle modifications, psychological support and specific treatment of any identified cause

g) Family history: women who miscarry, are more likely to have a family history of pregnancy loss.

h) More than 2/3rd of patients with RMC, will have a live birth in a subsequent pregnancy.

i) Signpost to: Miscarriage Association, Tommys: research at present includes: chronic endometritis, natural killer (NK) cells, sperm DNA fragmentation.

j) Provide written information; RCOG patient information leaflet:

- https://www.rcog.org.uk/globalassets/documents/patients/patient-information-leaflets/pregnancy/pi-recurrent-and-late-miscarriage---tests-and-treatment-of-couples.pdf

k) Counselling service: Cedar Tree (cedartreeworcs@gmail.com 01905 616166)

l) Direct access to EPAU in future pregnancies: serial growth scans and progesterone as indicated.

2) **Lifestyle advice** for couple: identify and correct any modifiable risk factors.
   a) Maintain healthy BMI 19-25; dietary advice if raised BMI. GP to refer to tertiary weight reduction clinic.
   b) Smoking cessation
   c) Limit alcohol consumption
   d) Limit caffeine to <200mg/day (≤3 cups a day)
   e) Advice not to take NSAIDs as this can disrupt ovulation
   f) Advice not to take aspirin or LMWH prior to 12 weeks in the absence of APS.
   g) Preconception Folic acid and Vitamin D 10mcg OD, should be advised, but do not prevent recurrent miscarriage.
   h) Stress – no evidence as direct cause for RMC.

3) Acquired thrombophilia - Antiphospholipid Syndrome (APS).

   a) Offer treatment: Aspirin 75mg (orally) at night and low molecular weight heparin (LMWH): 40mg (SC), from first positive pregnancy test until at least 34 weeks gestation. In most cases continue Aspirin until delivery and LMWH until delivery and 6 weeks postnatally.
   b) Patient to contact EPAU: for serial early reassurance USS.
   c) Treatment reduces miscarriage rate by 54% and increases live birth rate, with no adverse fetal outcomes.
   d) Even with treatment, pregnancies with APS remain high risk of complications (pre-eclampsia, fetal growth restriction and preterm birth).
   e) Aspirin: No adverse fetal outcomes reported in the studies of low dose aspirin for the prevention of pre-eclampsia in pregnancy. Heparin: does not cross the placenta, so no risk of fetal haemorrhage or teratogenicity.
   f) Side effects: bleeding, hypersensitivity reactions, and heparin-induced thrombocytopenia and when used long term, osteopenia and vertebral fractures (similar to physiological loss in pregnancy). Risk less with LMWH than unfractionated heparin.
   g) DO NOT GIVE aspirin/LMWH to women with unexplained RMC, as may increase risk.
   h) DO NOT USE: corticosteroids or IV immunoglobulin therapy as there is no benefit, and can be associated with significant maternal and fetal morbidity.

Patient weight (kg) or BMI	LMWH: ie Enoxaparin dose
<50 kg	20mg OD
50-90 kg	40mg OD
91-130 kg	60mg OD
131-170 kg	80mg OD
>170 kg	0.6mg/kg/day

4. Inherited thrombophilia.

   a) Do not use antithrombotic prophylaxis as there is no proven benefit; unless in the context of research or if necessary to reduce the risk of thrombotic events
   b) Due to the lack of data, thromboprophylaxis could be considered for women with Factor V Leiden, protein S deficiency and prothrombin gene mutation, when there are risk factors for thrombosis (as per Green-top Guideline No. 37a) and/or a history of second trimester miscarriage, particularly with evidence of placental thrombotic lesions. *This should first be discussed with the Haematology team*.

5. Abnormal fetal or parental karyotype

- Refer to Clinical Geneticist, and counselling.

a) They will discuss the prognosis for future pregnancies, and provide the opportunity for familial chromosome studies.
b) Reproductive options include prenatal diagnostic tests with IVF, gamete donation and adoption.
    - Preimplantation genetic testing for structural rearrangements (PGT-SR), formerly known as pre-implantation genetic diagnosis (PGD)
c) Preimplantation genetic screening with IVF for women with unexplained recurrent miscarriage does not improve live birth rate (30% verses 50-70% with natural conception) and should not be offered routinely. For the latest updates couples can visit the HFEA website (www.hfea.gov.uk).

6. Anatomical factors:

a) Uterine septum - hysteroscopic resection: consider in women with recurrent 1st or 2nd trimester miscarriage, ideally as part of research/audit. Observational studies have indicated significant benefit (reduced miscarriage, increased live birth rate, reduce preterm birth rate).
b) Acquired uterine anomalies: limited evidence to support the association with RMC or benefit of removal.
    a. Polyps: manage as general population (lack of evidence).
    b. Submucous fibroids: resection likely beneficial if distort cavity
    c. Intrauterine adhesions: potential benefit (lack of evidence).
c) Metroplasty for bicornuate uterus or reconstruction for unicornuate uterus are not recommended as there is no evidence of benefit.
d) Cervical factors: If history of second trimester miscarriage refer to preterm-pregnancy clinic for further management and surveillance with serial cervical length scans.
e) Endometrial scratch is not recommended as no evidence of benefit

7. Endocrine conditions:

a) DM: Optimise control: aim for HbA1c below 48 mmol/mol (6.5%). Provided this is achievable without causing problematic hypoglycaemia, and recommend 5 mg folic acid

b) Clinical hypothyroidism: Treat with Levothyroxine to reduce maternal and fetal complications. Most already on treatment. Consider increasing dose of Levothyroxine by 30-50% as soon as a positive pregnancy test is achieved.
    - If on thyroxine preconception – increase dose from first positive pregnancy test: by 25-50mcg daily (depending on the pre-pregnancy dose) – *as per WHAT-TP-094 Hypothyroism in pregnancy guideline.*

c) **MODERATE subclinical hypothyroidism (SCH) (TSH >4 mIU/l with a normal free thyroxine, +/-TPO): thyroxine supplementation should be offered** (see separate Fertility Thyroid Management Guideline).
    - **Mild SCH (TSH >2.5mIU/l, +/-TPO): insufficient evidence to support treatment.**
        i. **If positive TPO – need annual TSH with GP**
    - Regular TSH from 7-9 weeks (and in each trimester) is recommended in cases with SCH or positive TPO.
d) **Euthyroid with TPO** (normal TSH and TPO Ab+): thyroxine supplementation is not routinely recommended as per the TABLET study.

As per ROCG GTG No.17 & SIP No.70

e) PCOS: No treatment has been shown to improve outcome.

f) Treat hyperprolactinaemia with bromocriptine: increase live birth rate. Please refer to the Endocrine team so further investigations and treatment can be initiated (See Trust Fertility guideline on Prolactin)

8. Progesterone: PRISM & PROMISE Trials

a) RCOG: '*Women with a **history of miscarriage** who present with **bleeding** in early pregnancy may benefit from the use of progesterone.' – PRISM trial*
   a) 400 mg micronised vaginal progesterone BD until 16 weeks of gestation
b) Routine progesterone for unexplained miscarriage did not show any improvement in outcome. - *PROMISE trial.*
c) *However, if ≥4 previous miscarriages progesterone may provide some benefit*

Progestogen supplementation should be considered in women with recurrent miscarriage who present with bleeding in early pregnancy (for example 400 mg micronised vaginal progesterone twice daily at the time of bleeding until 16 weeks of gestation).	**1–**	**B**	The PRISM trial reported no significant differences in live births in women presenting with bleeding in early pregnancy and receiving progesterone supplementation; however, in the subgroup analysis of women with recurrent miscarriage, a significant improvement in live birth rate was observed.
Routine supplementation should be used with caution in asymptomatic women with unexplained recurrent miscarriage.	**1–**	**B**	Meta-analyses have reported a possible benefit from progestogen supplementation. However, there is a lack of consistently demonstrable benefit when used routinely in women with unexplained recurrent miscarriage, and there remains uncertainty about the optimal specific drug, route, timing and dose. The PROMISE trial, the largest multicentre RCT to date, which was adequately powered and with a very low risk of bias, showed that routine progesterone supplementation did not improve the outcome.

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*__PROMISE__ – explored the use of vaginal micronized progesterone on live birth rates in RMC. From first PPT until 12 weeks. It showed that progesterone supplements in the first trimester does not improve live birth rates in unexplained recurrent miscarriage. The live birth rate for women with 3 previous miscarriages was 67.9% in the progesterone group (65.8% if >3), verses 67.4% in the control group (63.3% if >3); difference not statistically significant.

- The subgroup analysis of higher order miscarriages (>4 miscarriages) found a live birth rate of 63.3% in the progesterone group (verses 58.3% in the placebo group). For 4, 5 or >6 miscarriages, there was an increased live birth rate of between 6.4% and 7.4%. These suggest a real benefit, but the difference was not statistical significant; therefore no strong recommendation can be made.

*__PRISM__ – explored threatened pregnancy loss, using progesterone from spotting until 16 weeks. It showed a small but positive treatment effect dependent on the number of pregnancy losses

Do not give unless as part of a RCT:

- Aspirin: evidence from the SPIN and ALIFE study showed that there is no benefit and there may even be a slight increase in future miscarriage amongst women whom do not have APS.
- LMWH: in unexplained recurrent miscarriage and inherited thrombophilia, is of no benefit.
- Human chorionic gonadotrophin for luteal phase insufficiency
- Immunotherapy (paternal cell immunization, 3rd party donor leucocytes, trophoblast membranes and IV IgG) Glucocorticoids or intralipid.
- Metformin for women with glucose metabolism defects: no benefit
- Endometrial scratch: no evidence of benefit
- Lymphocyte immunization therapy: may cause harm.

References:

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14. Brigham SA et al. A Longitudinal study of pregnancy outcome following idiopathic RMC. *Hum Reprod* 1999;14:2868-71.
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Useful Links and Support Groups

- Miscarriage Association: https://www.miscarriageassociation.org.uk/
- Tommy's: https://www.tommys.org/
- RCOG patient information leaflet:
  - https://www.rcog.org.uk/globalassets/documents/patients/patient-information-leaflets/pregnancy/pi-recurrent-and-late-miscarriage---tests-and-treatment-of-couples.pdf
- Counselling service: Cedar Tree (cedartreeworcs@gmail.com 01905 616166)

Appendix 1

CYTOGENETICS / KARYOTYPING SPECIMEN TO GO TO B'HAM WOMEN'S HOSPITAL

(Ideally, Specimen should be at Women's the same day. Lab shuts at 5pm so latest time for Taxi to leave here is about 3.30. If likely to be after that, then phone Lab and ask them what they want us to do with the Specimen)

TELEPHONE LAB: at B'ham Women's Hospital 0121 627 2710 or 0121 627 4776 to tell them Specimen is coming.

SPECIMEN: Separated by Surgeon from ERPC specimen trap. Needs approximately 1cm cube. Goes into dry Universal container, cover with Saline

SPECIMEN FORM: Blue "Cytogenetics Referral" (Available from Midwives in Clinic if none here)

WRAP SPECIMEN IN THE FORM and place in Padded envelope to "West Midlands Regional Genetics Laboratory" (Available from Midwives in Clinic if none here)

ORGANISE TAXI.

- Alexandra Switchboard
- Cost code 182620
- Authoriser "Inese Rowbotham"
- A "Human Tissue Specimen" to go to "Genetics Reception at Birmingham Women's Hospital"

(Switchboard at Alex organise all Taxis for whole Trust so be VERY careful to tell them where you are and where it's going.)

HAND SPECIMEN TO TAXI DRIVER and make sure he knows it is to go to "Genetics Reception at Birmingham Women's Hospital" NOT the main reception desk at the Hospital!

PHONE LAB AGAIN to tell them it's on the way.

Any problems please contact: Kevin Ward (OYEZ) Charge Nurse, Theatre 4 Kidderminster Treatment Centre (Int: 55392 Ext: 01562 512384) kevin.ward5@nhs.net

Appendix 2

Progesterone in Early Pregnancy

1. **Progesterone pessaries: Cyclogest 400mg bd pv**
   - Cyclogest use for this indication is off-label
2. Offer to all women with early pregnancy bleeding AND previous miscarriage (the more miscarriages, the greater the benefit).[1,2,5]

2. Start progesterone when an intrauterine pregnancy is seen on USS - do not need to wait for fetal heart[1]
   - USS should be arranged as soon as possible, but if it may be delayed, then progesterone should be started in the interim, and then continue/stop according to USS finding.
3. If a fetal heartbeat is then confirmed, continue progesterone until 16 completed weeks of pregnancy.[1]
4. No benefit of progesterone if early pregnancy bleeding and no previous miscarriage, so no proven benefit if give.[5]
5. If recurrent miscarriages (3x) and no bleeding - progesterone of no definite benefit
   - Can consider using progesterone with caution. [2,3]
   - Give to women with ≥4 miscarriages (ie higher order RM)[4]
   - Serial reassurance USS 7 and 9 wks (unless history of ectopic then USS at 6wks).

References and information to help with counselling:

1. NICE NG 126 (Ectopic Pregnancy and Miscarriage)
2. RCOG New GTG 17 - Recurrent Miscarriages
3. ESHRE GL
4. PROMISE Trial – summary for discussion

The subgroup analysis in women with higher order miscarriages (≥4 miscarriages) found a live birth rate of 63.3% in the progesterone group (verses 58.3% in the placebo group). If 4, 5 or ≥6 miscarriages are looked at individually, there was an increase live birth rate of between 6.4% and 7.4%. Although these figures all suggest a real benefit, none of these differences were statistically significant; therefore no strong recommendation can be made. Trial was designed to look for a 10% difference, a larger trial may detect a smaller difference [NICE].

5. PRISM Trial – summary for discussion

Women with early pregnancy bleeding and one or two miscarriages, when given progesterone until 16 weeks showed a 4% increase in number of babies born (verses placebo). Even greater benefit of 15% if bleeding and a history of recurrent miscarriages (≥3). https://www.youtube.com/watch?v=Khke7zMLmMg

6. Tommy's information leaflet to be given to patients – appendix 3

Appendix 3

EARLY PREGNANCY BLEEDING & PROGESTERONE

Progesterone is an effective treatment for women who have early pregnancy bleeding AND 1 or more previous miscarriages

20% OF WOMEN

Bleeding before 12 weeks can happen for about **20% of pregnant women.**

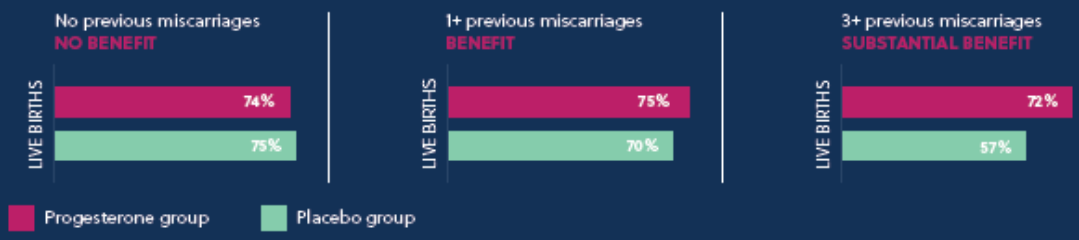
Although women are often worried at the sight of blood, **it is not always a sign of a problem.**

However, bleeding in early pregnancy does increase the risk of miscarriage.

What is progesterone? Progesterone is a natural hormone that is important during pregnancy; it helps to grow the lining of the womb and helps the mother's body to accept the growing baby.

A large UK-wide medical research trial* has now shown that **progesterone can prevent miscarriage** if you are bleeding in early pregnancy AND have a history of previous miscarriage.

Who was shown to benefit from progesterone treatment?



What is the treatment?

Progesterone (the drug used in the trial was called Utrogestan®) is taken as vaginal pessaries, 400mg twice daily, from the time you see a doctor with bleeding up to 16 weeks of pregnancy.

400mg 2xDAILY

Progesterone treatment is safe to use in pregnancy.

WHERE CAN I GET THIS TREATMENT?

If you are bleeding in early pregnancy:

- please call your Early Pregnancy Unit (EPU) at your local hospital and ask to be seen
- if your EPU is closed, visit your hospital Accident and Emergency unit
- bring this guidance with you or refer to www.tommys.org/PRISM.

This information was produced by Tommy's with the guidance of Professor Arri Coomarasamy and his team at the Tommy's National Centre for Miscarriage Research. The trial took place from May 2015 - 2017. Follow-up of patients was completed by June 2018. To find out more visit www.tommys.org/PRISM.

*PRISM Trial: Multi-centre randomised placebo-controlled trial of effects of vaginal progesterone in women with early pregnancy bleeding. Coomarasamy et al. (2019). A Randomized Trial of Progesterone in Women with Early Pregnancy Bleeding. N Engl J Med, May 2019.

This study was funded by the National Institute for Health Research (NIHR) HTA programme (project reference 12/167/26). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Tommy's

Appendix 4

Recurrent miscarriage: recommendations for practice

from the Lancet Series on Miscarriage

Investigating recurrent miscarriage

Four essential tests have been identified for investigating recurrent miscarriage:

Thyroid function

A blood test to check thyroid function. If overt hypo-thyroidism or hyper-thyroidism is identified, appropriate treatment can improve outcomes

Therapeutic benefit?

Yes

Lupus anticoagulant

Anticardiolipin antibodies

Both these blood tests assess for evidence of antiphospholipid antibodies. If positive, treatment with aspirin and low molecular weight heparin could improve outcomes

Therapeutic benefit?

Weak

Transvaginal pelvic ultrasound

An ultrasound test to identify uterine anomalies such as septum. However, there is no clear evidence treatment of septum improves outcomes

Therapeutic benefit?

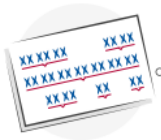
Unclear

In some cases, additional tests could also be useful:

Chromosome analysis

Chromosome analysis of pregnancy tissues can help identify abnormalities in the embryo, and help plan future care

Parental karyotyping



Chromosome analysis of the parents can help identify problems such as chromosome translocations, and help plan future care

Prevention

There is no high-quality evidence that any treatment is useful in preventing miscarriages in women at high risk of miscarriage, but evidence suggests some treatments could help:

Progesterone

Progesterone can increase livebirth rates for women who experience recurrent miscarriage

Quality of evidence

Moderate

Levothyroxine

Levothyroxine may decrease the risk of miscarriage in women with subclinical hypothyroidism

Quality of evidence

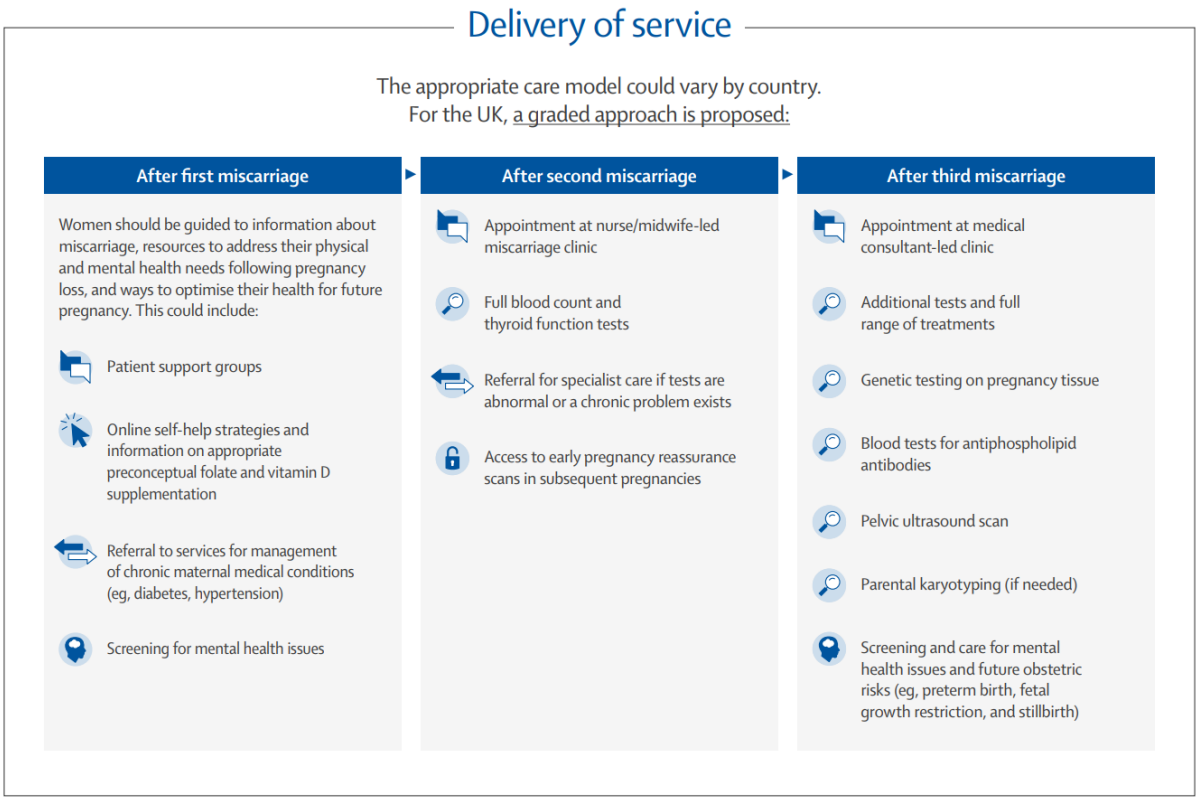
Low

Aspirin and heparin

A combination of aspirin and heparin may increase livebirth rates in women who have antiphospholipid antibodies

Quality of evidence

Low


Delivery of service
The appropriate care model could vary by country.
For the UK, a graded approach is proposed:
After first miscarriage
Women should be guided to information about miscarriage, resources to address their physical and mental health needs following pregnancy loss, and ways to optimise their health for future pregnancy. This could include:
Patient support groups
Online self-help strategies and information on appropriate preconceptual folate and vitamin D supplementation
Referral to services for management of chronic maternal medical conditions (eg, diabetes, hypertension)
Screening for mental health issues
After second miscarriage
Appointment at nurse/midwife-led miscarriage clinic
Full blood count and thyroid function tests
Referral for specialist care if tests are abnormal or a chronic problem exists
Access to early pregnancy reassurance scans in subsequent pregnancies
After third miscarriage
Appointment at medical consultant-led clinic
Additional tests and full range of treatments
Genetic testing on pregnancy tissue
Blood tests for antiphospholipid antibodies
Pelvic ultrasound scan
Parental karyotyping (if needed)
Screening and care for mental health issues and future obstetric risks (eg, preterm birth, fetal growth restriction, and stillbirth)

Worcestershire Acute Hospitals NHS Trust

Appendix 5 Miscarriage Investigation and Follow-up flowchart

1st MC

General Advice

Patient information leaflet
- Lifestyle & wellbeing
- Support
- EPAU contact number

In future pregnancies:
- If bleeding, consider progesterone* (& USS)
- Not for automatic reassurance USS (unless PVB)

2nd MC

General Advice & PIL

Investigations:
- Bloods: FBC, TSH & TPO
  - HbA1c & prolactin if clinical suspicion*
  - Request results under oncall consultant
  - List to be kept by EPAU nurses, to check results and action
  - Template results letter on Bluespier
  - Abnormal results: escalate via ward manager DW or KB

In future pregnancies:
- If bleeding, consider progesterone* (& USS)
- Future planning: Access to early reassurance USS

3rd MC

General advice and RCOG PIL

Refer to RMC Clinic:
- Set template on Bluespier; nurses to amend and send

Investigations:
- Bloods: FBC, TSH, TPO, HbA1c, prolactin* and APS
  - Request results under KB
  - Template results letter on Bluespier
- Send POC (if possible).
  - Results template letter on BS, if concerns refer to KB (paper copy of results via secretary please)

In future pregnancies:
- Self refer to EPAU
- If bleeding, consider progesterone* (& USS)
- Future planning/service development: Access to early reassurance USS

4th MC

General advice and PIL

Refer to RMC clinic if not already done
- Inform KB via secreatry if already under their care, unlikely need to be re-referred

Investigation:
- Bloods: only repeat if:
  - Thyroid and FBC >6m ago
  - HbA1c if >12m ago
  - ALS if >12-24m ago

In future pregnancies:
- Self refer to EPAU
- Offer progesterone* from PPT
- Serial growth scans at 7 &9 wks

≥5th MC

As for 4th MC

Additional investigations:
- Offer couple karyotyping if no products previously sent

As per *RCOG GTG17

If any clinical suspicion of ectopic pregnancy - for USS prior to progesterone

Progesterone:

Cyclogest pessaries (PV or PR) 400mg BD

from spotting until 16weeks.

MC=miscarriage, PVB= per vaginal bleed, PIL=patient information leaflet, KB=Kiritea Brown, DW=Danielle Williams, BS=Bluespier computer system, POC=products of conception, PPT=positive pregnancy test, APS=Antiphospholipid syndrome

Appendix 6

Clinic Date: **Consultant:** **Couple seen together: Y/N**

Female name *ID Sticker*		**Occupation**
Hospital/ NHS Number		**Age**
DOB		

Partner name *ID Sticker*		**Occupation**
Hospital/NHS Number		**Age**
DOB		

Married		**Related to partner**	
Duration of relationship			

Fertility complaint		
Duration of subfertility: **LMP:**	**P + **	**Age at Menarche:**
Regular cycle: _____ /	**Irregular cycle:**	**IMB/HMB/Dysmen**
Previous Contraception:	**Stopped:**	
History:		
Intercourse frequency: /wk	**Advice on frequency:**	**Problems:** *PCB/Dyspareunia/male factor*

Obstetric History				
Date:	Outcome:	Gestation:	Management, treatment, histology:	Current partner:

Medical History			
PMH:			
Known APS:			
Known thrombophilia:			
Surgical History:			
Previous VTE	Date:	Treatment:	
DH:		Illicit drugs:	
Allergies:		Reaction:	
Folic Acid	400microg/d	5mg/day (BMI>29 or PMH)	Advice to start: Yes
Smear:	Date:	Result:	Previous treatment:
FH: VTE			
Other: Symptoms of hyperprolactinaemia			
Previous Fertility Investigation/treatments:			

Lifestyle							
Female patient				**Partner**			
BMI (spreadsheet if <19 or >29):			_____	**BMI (spreadsheet if <19 or >29):**			_____
Ht cm		**Wt** kg		**Ht** cm		**Wt** kg	
Smoker	**Y/N** **Ex:**	**Number:** **/day** **Smoking cessation Ref**		**Smoker**	**Y/N** **Ex:**	**Number:** **/day** **Smoking cessation Ref**	
Caffeine consumption:							
Exercise:							
Exposure to toxins:							
Alcohol consumption /wk **Advice given:**				**Alcohol consumption** /wk **Advice given**			

Partner History		
Medical conditions:		
Testicular problems/surgery:		
Vasectomy/reversal:		
Previous Infections/STIs:		
Children from previous relationships?	**Difficulty in conceiving?**	
Previous Fertility Investigations / Treatment:		
DH:	**Illicit drugs:**	**Allergies:** Reaction:

Examination: Female	**Partner**

Initial Plan and Advice given			
Investigation:	**Date:**	**Result:**	**Requested Today:** √
FSH			
LH			
Testosterone			
Prolactin			
TSH			
AMH			
Progesterone | Day:			
Rubella Immunity			
Chlamydia			
TVUSS (Natural or OI)			
HSG or Lap&Dye			*Leaflet given [ ]*
Semen Analysis:			*Leaflet given [ ]*
Total count: >39M 1)	Motility: Total >40% Progressive >32%		Morph >4%
Andrology			*Leaflet given [ ]*
Recurrent Miscarriage Investigations:			
APL antibodies			
Thrombophilia screen			
FBC			
HbA1c			
TSH & TPO antibodies			
TVUSS			
Karyotyping			

Medications commenced:			
Clomiphene	50/100/150mg OD day 2-6 for _____ months		*Leaflet given [ ]*
Letrazole	2.5/5/7.5mg OD day 2-6 for _____months		*Leaflet given [ ]*
OI with FSH Menopur			*Leaflet given [ ]*
MPA	10mg tds for 7days (after neg PT on day 35)		*Leaflet given [ ]*
Folic Acid/Vit D	400microg or 5mg (if indicated by PMH)		
Metformin			
Other:			
Other leaflets given:	*Clinic visit sheet*	*Lifestyle advice sheet*	*Weight loss sheet*
	IVF/ICSI	*RCOG RMC leaflet*	*Cedartree contact details*

Follow-Up and Further Care:		
Initial Plan:		
Fertility clinic follow-up		
Referral to:	ART: NHS / Private	Pre-pregnancy counselling:

Plan for next pregnancy for Recurrent Miscarriage patients:	
[ ] General Advice	BMI, smoking, alcohol, NSAIDs RCOG information leaflet and Cedar Tree Counselling service details
[ ] Unexplained	1. Reassurance and supportive care in EPAU, no evidence that any specific medical treatment improves outcome. 2. Self-referral to EPAU for serial early USS
[ ] Progesterone	Consider progesterone: vaginal micronized Cyclogest 400mg bd pv/pr from spotting until 16 weeks (off-label use) Limited evidence but ? beneficial if >4 miscarriages and no spotting
[ ] APS confirmed	1. Self-referral to EPAU for serial early USS 2. Review to commence Aspirin and LMWH. Stop aspirin at delivery, continue LMWH until 6 weeks postnatally.
[ ] Inherited thromb:	No evidence of benefit from treatment with LMWH & Aspirin.
[ ] NK cells	Potential treatments in early stages of research. • Offer information: Professor. S Quenby runs a private clinic at Coventry and Warwick Hospital; costing in the region of £600.
Other:	

Sign, print, GMC number, date:	

Monitoring

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the Policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: (Responsible for also ensuring actions are developed to address any areas of non-compliance)	Frequency of reporting:
	WHAT?	HOW?	WHEN?	WHO?	WHERE?	WHEN?
	Accurate management and understanding of causes, to ensure correct information and counselling of patients	Audits, patient feedback, analysis of any incidents via datix/complaints	Whenever necessary pending feedback	Fertility Lead and Lead Fertility Nurse	Fertility MDT	Whenever necessary following incidents

Supporting Document 1 - Equality Impact Assessment Tool

Equality and Health Inequalities Impact Assessment (EHIA) Tool

Herefordshire & Worcestershire STP - Equality and Health Inequalities Impact Assessment (HEIA) Form
Please read HEIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council	
Worcestershire Acute Hospitals NHS Trust	✠	Worcestershire County Council	
Worcestershire Health and Care NHS Trust	·	Wye Valley NHS Trust	
Other (please state)	·		

Name of Lead for Activity	K Brown

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
	Kiri Brown	O&G Consultant	Kiritea.brown@nhs.net
Date assessment completed	26.1.26		

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title:** Recurrent Miscarriage Guideline				
What is the aim, purpose and/or intended outcomes of this Activity?	To ensure correct management and investigation of patients suffering multiple miscarriages.				
Who will be affected by the development & implementation of this activity?	☒ ☒ ❑· ❑·	Service User Patient Carers Visitors	☒ ☒ ❑· ❑·	Staff Communities Other _____	
Is this:	☒ Review of an existing activity ❑ New activity ❑ Planning to withdraw or reduce a service, activity or presence?				
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.	References as above				

Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	Agreed in Fertility MDT, the MSC and Gynae Governance
Summary of relevant findings	As per GL

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age	y			
Disability	y			
Gender Reassignment	y			
Marriage & Civil Partnerships	y			
Pregnancy & Maternity	y			Agreed in Gynae Governance
Race including Traveling Communities	y			
Religion & Belief	y			
Sex	y			
Sexual Orientation	y			
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)	y			
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)	y			

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
		.		
How will you monitor these actions?	**Review and investigate as per any concerns via datix and complaints**			
When will you review this HEIA? (e.g in a service redesign, this HEIA should be revisited regularly throughout the design & implementation)	GL will be reviewed every 3 years, or earlier if new guidance available			

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing HEIA	
Date signed	26.1.26
Comments:	
Signature of person the Leader Person for this activity	
Date signed	26.1.26

Comments:	

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	N
2.	Does the implementation of this document require additional revenue	N
3.	Does the implementation of this document require additional manpower	N
4.	Does the implementation of this document release any manpower costs through a change in practice	N
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	N
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval.