Investigation and Treatment of Couples with Recurrent Miscarriage
Clinical Guideline

V2.0

July 2020
1. Aim/Purpose of this Guideline

1.1. For all clinical staff working in the Women and Children’s Care Group to provide evidence based guidance in the management of miscarriages.

1.2. This version supersedes any previous versions of this document.

Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the DPA18 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed and documented. We cannot rely on opt out, it must be opt in.

DPA18 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the DPA18 please see the Information Use Framework Policy or contact the Information Governance Team rch-tr.infogov@nhs.net

2. The Guidance

2.1. Investigation and treatment of couples with recurrent miscarriage

Miscarriage is defined as the loss of a pregnancy before the fetus reaches viability (usually before 24 weeks gestation). Recurrent miscarriage is the occurrence of three or more miscarriages. It affects 1% of all women. A persistent underlying cause is only found in a small proportion of women with recurrent miscarriage. Increasing maternal age and the number of previous miscarriages are independent risk factors for a further miscarriage.

2.2. Investigations that should be arranged

- Maternal Antiphospholipid syndrome screen (present in 15% women with recurrent miscarriage). Request anticardiolipin antibody & lupus anticoagulant screen (2 x blue topped and 2 x yellow topped tubes). A full thrombophilia screen is unnecessary at this stage, and will be rejected by the lab. Please inform the woman that if positive, a repeat test should be arranged 12 weeks later before the diagnosis of antiphospholipid syndrome can be made.

- Karyotyping of conceptus. This is recommended on the pregnancy tissue of any recurrent miscarriage. Be sure to send the sample in the correct HAMS medium (available from Wheal Rose freezer) – NOT normal saline – see Appendix 3). You will need to ensure maternal consent for this (see specific consent form Appendix 4). This should not alter their choice of management of miscarriage, although if they wish to manage the miscarriage expectantly, they should be advised to bring the sample to
EGU the next working day and in the meantime to store in the fridge, dry, in a clean container.

- Pelvic ultrasound scan (TVS) to assess uterine anatomy and morphology when not pregnant.

### 2.3. Investigations which should NOT be arranged routinely:

- Parental karyotype – unless Karyotype of conceptus reveals an unbalanced translocation
- Glucose tolerance test for diabetes in asymptomatic women
- Thyroid function tests and thyroid antibody screening for thyroid disease in asymptomatic women
- Prolactin levels in menstruating women
- TORCH screening
- Screening for (and treatment of) bacterial vaginosis

### 2.4. Recommended treatments supported by evidence

In women with a history of recurrent miscarriage and antiphospholipid antibodies, future live birth rate is significantly improved when a combination therapy of aspirin plus heparin is prescribed. Such women should be discussed with the haematologists and managed jointly as they are high risk pregnancies, not only for recurrent miscarriages, but also for pre-eclampsia, intrauterine growth restriction and pre-term birth.

### 2.5. Advice to women with a history of recurrent miscarriage

- Women with unexplained recurrent miscarriage have an excellent prognosis for a successful future pregnancy (around 75%) without pharmacological intervention if offered supportive care alone in the setting of a dedicated early pregnancy assessment unit.
- Offer progesterone (400mg PV / PR once daily) to women with a history of 3 or more miscarriages (lifetime not necessarily consecutive) who present with a history of vaginal bleeding and a scan which shows evidence of a viable intrauterine pregnancy or a pregnancy of uncertain viability. This should be continued up to 12 weeks gestation

### 2.6. Treatments which should NOT be employed routinely in women with a history of recurrent miscarriage: (as there is insufficient evidence)

- Cervical cerclage
- hCG supplementation in early pregnancy
• Prepregnancy pituitary suppression of LH
• Immunotherapy in women with previous unexplained recurrent miscarriage
• Metformin in women with PCOS

2.7. Summary

Recurrent miscarriage is a very distressing problem. The above investigations can be arranged at the time of their third miscarriage and follow up arranged in EGU for results & counselling. Please be sure to write clear instructions on the discharge letter to the GP and enter their name in the EGU diary to ensure follow up arranged.

3. Monitoring compliance and effectiveness

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>The outcome &amp; success of different managements of miscarriage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>Miss Lisa Verity, Consultant O&amp;G</td>
</tr>
<tr>
<td>Tool</td>
<td>Miscarriage database &amp; Gynaecology dashboard on Q drive</td>
</tr>
<tr>
<td>Frequency</td>
<td>Annually</td>
</tr>
<tr>
<td>Reporting arrangements</td>
<td>EGU / EPU MDT</td>
</tr>
<tr>
<td>Acting on recommendations and Lead(s)</td>
<td>EGU / EPU MDT</td>
</tr>
<tr>
<td>Change in practice and lessons to be shared</td>
<td>Required changes to practice will be identified and actioned within 3 months. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders</td>
</tr>
</tbody>
</table>

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Inclusion & Human Rights Policy' or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.
## Appendix 1. Governance Information

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Investigation And Treatment Of Couples With Recurrent Miscarriage Clinical Guideline V2.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>This document replaces (exact title of previous version):</td>
<td>Investigation And Treatment Of Couples With Recurrent Miscarriage - Clinical Guideline V1.1</td>
</tr>
<tr>
<td>Date Issued/Approved:</td>
<td>July 2020</td>
</tr>
<tr>
<td>Date Valid From:</td>
<td>July 2020</td>
</tr>
<tr>
<td>Date Valid To:</td>
<td>July 2023</td>
</tr>
<tr>
<td>Directorate / Department responsible (author/owner):</td>
<td>Miss Lisa Verity Consultant O&amp;G</td>
</tr>
<tr>
<td>Contact details:</td>
<td>01872 252685</td>
</tr>
<tr>
<td>Brief summary of contents</td>
<td>Guideline for all clinical staff working in the Women and Children’s Care Group to provide evidence based guidance in the management of miscarriages.</td>
</tr>
<tr>
<td>Suggested Keywords:</td>
<td>Recurrent miscarriage couples treatment</td>
</tr>
<tr>
<td>Target Audience</td>
<td>RCHT</td>
</tr>
<tr>
<td>Executive Director responsible for Policy:</td>
<td>Medical Director</td>
</tr>
<tr>
<td>Approval route for consultation and ratification:</td>
<td>Obstetric &amp; Gynaecology Directorate meeting</td>
</tr>
<tr>
<td>General Manager confirming approval processes</td>
<td>Mary Baulch</td>
</tr>
<tr>
<td>Name of Governance Lead confirming approval by specialty and care group management meetings</td>
<td>Caroline Amukusana</td>
</tr>
<tr>
<td></td>
<td>RCOG Guideline No 17. The investigation and treatment of couples with recurrent first-trimester and Second-Trimester miscarriage. April 2011</td>
</tr>
<tr>
<td></td>
<td>Peninsula EGU / EPU Consensus statement following publication of PRISM</td>
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</table>
Training Need Identified? | No
--- | ---
Publication Location (refer to Policy on Policies – Approvals and Ratification): | Internet & Intranet  ✔ Intranet Only
Document Library Folder/Sub Folder | Clinical / Gynaecology

**Version Control Table**

<table>
<thead>
<tr>
<th>Date</th>
<th>Version No</th>
<th>Summary of Changes</th>
<th>Changes Made by (Name and Job Title)</th>
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<tr>
<td>13/06/2014</td>
<td>V1.0</td>
<td>Initial Issue</td>
<td>Lee Azancot  Data Administrator</td>
</tr>
<tr>
<td>11/04/2017</td>
<td>V1.1</td>
<td>Minor changes</td>
<td>Lisa Verity  Consultant</td>
</tr>
<tr>
<td>June 2020</td>
<td>V2.0</td>
<td>Full Review. Updated to current Trust template. Minimal changes – section 2.2 confirmation of where to send sample, offer of progesterone added to section 2.5, Progesterone supplementation removed from section 2.6</td>
<td>Lisa Verity  Consultant</td>
</tr>
</tbody>
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**All or part of this document can be released under the Freedom of Information Act 2000**

**This document is to be retained for 10 years from the date of expiry.**

**This document is only valid on the day of printing**

**Controlled Document**

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies). It should not be altered in any way without the express permission of the author or their Line Manager.
### Appendix 2. Initial Equality Impact Assessment Form

<table>
<thead>
<tr>
<th>Name of the strategy / policy / proposal / service function to be assessed:</th>
<th>Investigation And Treatment Of Couples With Recurrent Miscarriage Clinical Guideline V2.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directorate and service area:</td>
<td>Gynaecology</td>
</tr>
<tr>
<td>Is this a new or existing Policy?</td>
<td>Existing</td>
</tr>
<tr>
<td>Name of individual/ group completing EIA</td>
<td>Miss Lisa Verity</td>
</tr>
<tr>
<td>Contact details:</td>
<td>01872 252685</td>
</tr>
</tbody>
</table>

1. **Policy Aim**
   - Who is the strategy / policy / proposal / service function aimed at?
   - To provide evidence based guidance in the management of couples experiencing recurrent miscarriages for all clinical staff working in the Women and Children’s Care Group.

2. **Policy Objectives**
   - As above

3. **Policy intended Outcomes**
   - As above

4. **How will you measure the outcome?**
   - See section 3

5. **Who is intended to benefit from the policy?**
   - All obs & gynaec patients

6a). **Who did you consult with**

6b). **Please identify the groups who have been consulted about this procedure.**
   - Workforce
   - Patients
   - Local groups
   - External organisations
   - Other
   - Obstetric & Gynaecology Directorate meeting

6c). **What was the outcome of the consultation?**
   - Guideline approved
### 7. The Impact

Please complete the following table. If you are unsure/don’t know if there is a negative impact you need to repeat the consultation step.

**Are there concerns that the policy could have differential impact on:**

<table>
<thead>
<tr>
<th>Protected Characteristic</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
<th>Rationale for Assessment / Existing Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Sex (male, female non-binary, asexual etc.)</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Gender reassignment</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Race / ethnic communities /groups</td>
<td></td>
<td></td>
<td>X</td>
<td>Any information provided should be in an accessible format for the patient’s needs – i.e. available in different languages if required/access to an interpreter if required</td>
</tr>
<tr>
<td>Disability - (learning disability, physical disability, sensory impairment, mental health problems and some long term health conditions)</td>
<td></td>
<td></td>
<td>X</td>
<td>Those patients with any identified additional needs will be referred for additional support as appropriate - i.e to the Liaison team or for specialised equipment. Written information will be provided in a format to meet the family’s needs e.g. easy read, audio etc</td>
</tr>
<tr>
<td>Religion / other beliefs</td>
<td></td>
<td></td>
<td>X</td>
<td>All staff should be aware of any beliefs that may impact on treatment</td>
</tr>
<tr>
<td>Marriage and Civil partnership</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Pregnancy and maternity</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Sexual Orientation, (bisexual, gay, heterosexual, lesbian)</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

If all characteristics are ticked ‘no’, and this is not a major working or service change, you can end the assessment here as long as you have a robust rationale in place.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

**Name of person confirming result of initial impact assessment:**

Lisa Verity

If you have ticked ‘yes’ to any characteristic above OR this is a major working or service change, you will need to complete section 2 of the EIA form available here:

[Section 2. Full Equality Analysis](#)

For guidance please refer to the Equality Impact Assessments Policy (available from the document library) or contact the Human Rights, Equality and Inclusion Lead debby.lewis@nhs.net
Appendix 3 Cytogenic Testing

Consent for Cytogenetic testing
Written consent is mandatory using the designated consent form (see Appendix 4) and available in the Emergency Gynaecology Unit and in the Consent section of the Gynaecology intranet shared drive).

Cytogenetic Sample Pots
Universal containers containing specific transport medium ("For skin biopsy") are stored at -20°C in the fridge freezer in the Bereavement room on Wheal Rose ward.
Do not use the CVS medium.
The medium is thawed before the sample is placed in the pot
Pots are stored in the Bereavement room fridge (not freezer) until transfer to Bristol.

Technique for sample collection
Use a gloved non sterile technique with care to minimise contamination.

The sample is placed into thawed “skin biopsy” transport medium, ensure the lid is secured and label accurately.

Sample handling after collection
A cytogenetics request form is accurately completed with full details of clinical picture (eg. recurrent miscarriage) and referrer.
Samples (in a sealed plastic bag) are placed in the Bereavement room fridge, not the freezer compartment.
The sample is returned to Wheal Rose and the person collecting the sample records the woman’s name, CR number, date and time of sample collection and their name, designation and signature in the Cytogenetics Sampling Record book in the Bereavement room.
The Wheal Rose ward clerk will record the tracking log number in the Cytogenetics Sampling Record book when the samples are transferred to the post room.

Samples are boxed up by the Wheal Rose ward clerk (sealed with Pathological Specimen Fragile With Care tape), addressed to Regional Cytogenetics Centre, Southmead, Bristol BS10 5NB and sent at 0830-1430 week days and 0800-1100 Saturday to the RCH post room for special delivery transfer.

Documentation
The clinician documents discussion of consent in the notes and files the consent form.
The Cytogenetics ledger on Wheal Rose must be completed by the person taking the sample. This is a Human Tissue Authority (HTA) requirement.
Appendix 4.

Cornwall and Isles of Scilly Healthcare Community

Consent for Pregnancy Tissue Samples for Genetic Testing

- I understand that these samples are sent to the Regional Genetics Laboratory in Bristol for analysis

- I understand that the laboratory will report on the number of chromosomes in each cell and assess their size and shape. This information may be important in understanding what has happened in this pregnancy and advising you for future pregnancy

- I understand that there is a possibility that the cells may not grow in the laboratory and no result may be obtained

- I have had the opportunity to ask questions and have had them fully answered to my satisfaction

- I understand that a tiny sample of tissue (DNA or cultured cells) will be stored long term for the possibility of new genetic tests in the future that may help in a further pregnancy. No further testing will be undertaken without your permission

SIGNED:________________________________________________________

NAME:____________________DATE:________________

Witnessed by:

SIGNED:________________________________________________________

NAME:____________________DATE:________________