

## **D.6 Use of diagnostic tests including imaging, biomarkers and surgical diagnosis**

| <b>Item</b>           | <b>Details</b>  |
|-----------------------|---|
| Key area in the scope | Use of diagnostic tests including imaging, biomarkers and surgical diagnosis. |

| Item   | Details  |
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| Review question in the scope                           | <p>What is the accuracy of the following tests in diagnosing endometriosis:</p> <ul style="list-style-type: none"> <li>• imaging</li> <li>• biomarkers</li> <li>• surgical diagnosis?</li> </ul>   |
| Objective  | To evaluate the accuracy of diagnostic tests for the diagnosis of endometriosis in women with suspected endometriosis.   |
| Population   | <p>Symptomatic and asymptomatic women with suspected endometriosis</p> <p>Symptomatic<br/>Dyspareunia (pain on intercourse), deep dyspareunia (pain on entry), dyschezia (pain on bowel actions), rectal bleeding, cyclical bleeding, dysmenorrhea, painful periods</p> <p>Cyclical/non-cyclical symptoms</p> <p>Asymptomatic:</p> <ul style="list-style-type: none"> <li>• women who have an appendicitis removed (or any other abdominal surgery) with the finding of an endometrioma or endometriosis</li> <li>• Women who have a scan for other reasons with the finding of an endometrioma or endometriosis</li> <li>• women who have a ureteric obstruction</li> <li>• Women presenting with symptoms similar to IBS</li> <li>• Infertility investigations can discover endometriosis</li> </ul>   |
| Subgroups and sensitivity analyses                     | <p>The following groups will be assessed separately:</p> <ul style="list-style-type: none"> <li>• subgroups of women with different presenting symptoms of endometriosis (subfertility, pelvic pain, ovarian mass, asymptomatic women)</li> <li>• deep endometriosis vs superficial endometriosis</li> <li>• Methodological changes in practice; scanning techniques and advances in equipment</li> </ul>  |
| Index test: Severity assessment tools/clinical markers | <p>(1) Imaging (see subgroup above):</p> <p>Ultrasound (visual):</p> <ul style="list-style-type: none"> <li>• transabdominal</li> <li>• transvaginal</li> <li>• rectal scanning</li> </ul> <p>MRI:</p> <ul style="list-style-type: none"> <li>• pelvic MRI</li> </ul> <p>(2) Biomarkers:</p> <ul style="list-style-type: none"> <li>• biomarker cancer antigen 125 (CA-125, cut-off <math>\geq 35</math>U/ml)</li> <li>• biomarker Human epididymis protein 4 (HE- 4)</li> </ul> <p>(3) Biomarkers in endometrial tissues (the nerve fibre marker Protein Gene Product 9.5 (PGP 9.5)</p> <p>(4) Surgical diagnosis with or without histological confirmation:</p> <ul style="list-style-type: none"> <li>• combination of tests need to be considered, a clean scan is not always conclusive – an abnormal scan however can stand on its own.</li> </ul> |
| Reference standard or target                           | Surgical visualisation with histological confirmation  |

| Item                           | Details  |
|--------------------------------|--|
| condition/patient outcomes     |  |
| Outcomes                       | <ul style="list-style-type: none"> <li>• sensitivity</li> <li>• specificity</li> </ul> For continuous outcomes: <ul style="list-style-type: none"> <li>• area under the Curve</li> </ul>   |
| Importance of outcomes         | Critical outcomes: <ul style="list-style-type: none"> <li>• sensitivity</li> <li>• specificity</li> </ul> If there were any test-and-treat trials: <ul style="list-style-type: none"> <li>• quality of life</li> </ul>   |
| Study design                   | Systematic reviews<br>Randomised controlled trials (test and treat trials)<br>Cross sectional studies<br>Cohort studies<br>Case control studies will be excluded   |
| Population size and directness | Studies with indirect populations will not be considered   |
| Search strategy                | Sources to be searched: Medline, Medline In-Process, CENTRAL, CDSR, DARE, HTA, Embase<br>Limits (e.g. date, study design): Limit to English language and human-only studies where appropriate<br>Supplementary search techniques: No supplementary search techniques will be used.<br>See appendix for full strategies   |
| Review strategy                | Appraisal of methodological quality: <ul style="list-style-type: none"> <li>• The methodological quality of each study should be assessed using quality checklists (eg AMSTAR for systematic reviews, Cochrane RoB tool for RCTs, QUADAS2 for diagnostic studies) and the quality of the evidence for an outcome (i.e. across studies) will be assessed using GRADE.</li> </ul> Synthesis of data: <ul style="list-style-type: none"> <li>• Meta-analysis of diagnostic test accuracy tests will be conducted where appropriate</li> </ul> |
| Equalities                     | Adolescents are noted as a specific subgroup requiring consideration in the equalities impact assessment   |