Clinical statement on new diagnostic technologies for endometriosis in primary care

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The RCOG notes the recent press release from NICE announcing draft early-use guidance for consultation on new diagnostic technologies for endometriosis in primary care. It is essential to underline that this is *draft guidance, issued specifically for consultation*, not final NICE approval or full endorsement. NICE has indicated that use of these tests in the NHS will be accompanied by an evidence-generation period, during which their clinical effectiveness, safety and impact on care pathways will continue to be assessed before any longer-term recommendations are made. The RCOG fully shares NICE's aim of shortening the long delays many women face in receiving an endometriosis diagnosis and of exploring non-invasive approaches that might reduce the need for diagnostic laparoscopy in appropriate circumstances.

The saliva-based microRNA test (Endotest) has reported high diagnostic accuracy in published studies involving carefully selected groups of women with long-standing pelvic pain who are already at high risk of endometriosis, suggesting potential to reduce the need for laparoscopy in that specific context. However, these studies have largely been conducted in specialist centres and in populations preselected for a high likelihood of endometriosis, and most of the evidence to date comes from teams linked to the test's developer in France. Robust, independent validation in other countries, age and ethnic groups and routine clinical pathways, including general gynaecology and primary care settings where pelvic pain has multiple possible causes, is still limited and urgently needed.

The RCOG also notes the draft guidance covering the EndoSure test, which is being promoted as a rapid, non-invasive diagnostic tool for endometriosis with very high reported accuracy. At present, the strongest claims for near-perfect performance arise mainly from small studies led by the test's developers rather than large, independent, peer-reviewed trials. The underlying concept that endometriosis might generate a distinctive "electrical fingerprint" in the gut is scientifically interesting, but both the biological mechanism and the test's real-world performance have yet to be thoroughly validated in everyday clinical environments where a wide range of conditions can present with pelvic or abdominal pain. On this basis, and in line with usual standards for changing national diagnostic practice, the RCOG considers the EndoSure test to be experimental at this stage and advises that it be used and interpreted with caution.

The RCOG strongly supports NICE's decision to link early use of these technologies to structured evidence generation and ongoing review. Independent, high-quality studies across diverse populations and clinical settings will be essential before these tests can be regarded as established diagnostic tools or integrated widely into routine pathways of care for women with suspected endometriosis.