Ovarian cancer is one of the most common malignancies in women and the leading cause of gynaecological cancer death in the United Kingdom. More than 80% of cases are diagnosed in women aged over 50 years. Epithelial ovarian cancer is the most common form of the disease (accounting for over 85% of cases). There were 5,704 women diagnosed with ovarian cancer in England and Wales in 2008. Early symptoms are often absent or non-specific, and over 70% of women already have advanced disease by the time they are diagnosed. Overall outcomes are poor, with a 5 year survival rate of 41% in England. In 2008 ovarian cancer caused 3,824 deaths in England and Wales.

This news brief is based on information available at the time of research and a limited literature search. It is not intended to be a definitive statement on the safety, efficacy or effectiveness of the health technology covered and should not be used for commercial purposes or commissioning without additional information.

**Background**

Ovarian cancer is one of the most common malignancies in women and the leading cause of gynaecological cancer death in the United Kingdom. More than 80% of cases are diagnosed in women aged over 50 years. Epithelial ovarian cancer is the most common form of the disease (accounting for over 85% of cases). There were 5,704 women diagnosed with ovarian cancer in England and Wales in 2008. Early symptoms are often absent or non-specific, and over 70% of women already have advanced disease by the time they are diagnosed. Overall outcomes are poor, with a 5 year survival rate of 41% in England. In 2008 ovarian cancer caused 3,824 deaths in England and Wales.

**Current Practice**

Women whose symptoms are suggestive of ovarian cancer are assessed by physical examination of the vagina, anus and rectum, transvaginal ultrasound, a CA-125 blood test and computed tomography. Diagnosis is usually confirmed by surgery and ovarian biopsy.

**New Technology**

OVA1™, developed by Vermillion Inc and licensed to Quest Diagnostics, is a qualitative serum test that combines the results of 5 biomarker immunoassays into a single score which indicates the probability that ovarian cancer is present. The biomarkers are CA-125, prealbumin, apolipoprotein A-1, β2-microglobulin and transferrin. Blood samples are sent to Quest Diagnostic’s laboratory in the United States for analysis with results available in 5-7 days. A computer algorithm is used to give a single numerical score (ranging from 0 to 10). A score of ≥5.0 in pre-menopausal women and ≥4.4 in post-menopausal women indicates a high risk that ovarian cancer may be present.
OVA1™ is CE marked, but not yet available in the United Kingdom. Cost information was not available at the time of writing.

**Company update on cost - February 2012**
The list price of the test in the USA is $650 (approximately £420) per test. Medicare currently reimburse at a rate of $516.25 (approximately £335).

**Clinical Studies and Research Questions**
A multicentre, prospective, double-blind, clinical validity study in the United States reported by Vermillion Inc7,8 compared the accuracy of OVA1™ with standard pre-operative evaluation in 516 women with detected ovarian lumps for whom surgery was planned. The addition of OVA1™ to standard testing where diagnosis was confirmed by a specialist cancer surgeon, increased sensitivity from 60% to 89% in pre-menopausal women and from 81% to 98% in post-menopausal women. The addition of OVA1™ also improved negative predictive values from 85.5% to 97.6%, which indicates that OVA1™ may be useful for ruling out disease.

**Company update on trials - February 2012**


Ueland F, Goodrich S, Desimone C et al. Predicting the risk of malignancy for an ovarian tumor by combining imaging and OVA1. 17th Annual European Society of Gynecologic Oncology (ESGO) meeting September 2011.

**Potential Impact**

OVA1™ may increase the accuracy of pre-operative assessment to determine the probability that a pelvic lump that has been detected may be due to ovarian cancer. This may help to guide decision-making about the most appropriate specialist care that is needed, and could lead to improved health outcomes for patients10.

There would be increased direct costs related to this additional testing, but with the potential for savings arising from increased efficiency in specialist cancer services.
Lay summary

The Ova1 test is a new blood test for ovarian cancer. It is designed to be used when a lump that might be cancer of the ovary has been found and surgery is planned. Currently doctors use a combination of ultrasound and X-ray scanning, together with a blood test for one particular chemical linked with ovarian cancer, to predict whether cancer is present. The new test looks for the blood levels of five different chemicals – or ‘biomarkers’ – then combines these levels to give a score from 0 to 10. The score is intended to predict how likely it is that the woman has ovarian cancer. This information, together with scan results, is designed to help the woman’s doctor make the best decisions about how to treat her. A study has shown that, when added to the usual tests, the new test may help doctors decide if cancer is present. More studies are needed to show whether using this test routinely would really benefit women and the NHS.

References


