PRE-ECLAMPSIA BLOOD TEST

How an integrated team improved the safety of mothers and babies using angiogenic biomarkers for pre-eclampsia.

An Oxford team that developed and introduced a new blood test to rule out pre-eclampsia in pregnant women at Oxford University Hospitals NHS Foundation Trust (OUH) has won a UNIVANTS of Healthcare Excellence Award. The award recognises "teams that collaborate across disciplines, including the core laboratory, to reshape care pathways and ultimately achieve better outcomes for patients, clinicians, payers and entire health systems".

The team, including IBMS Fellow, Tim James, Head Biomedical Scientist in OUH's clinical biochemistry department, trialled the test at the John Radcliffe Hospital's Women's Centre. A key finding is that the test predicts that a pregnant woman will not develop pre-eclampsia

within the next seven days with almost 100% accuracy. It was accepted as routine clinical practice at OUH in 2018 and is now being rolled out across the NHS by the Oxford Academic Health Science Network (AHSN).

Significant strides

The test demonstrates how clinical chemists can make significant strides in improving care. Tim James' role was to support the clinical trial (The INSPIRE study), manage a business case for introduction into routine practice in Oxford, and support the Oxford AHSN in helping other labs set up the test. He says: "One of the important things we have learnt is that the new test helps clinicians make important decisions about patient care at a critical stage of pregnancy and in many cases reduces uncertainty about those decisions. We are, therefore, keen to make sure the test benefit can be delivered across the NHS."

Pre-eclampsia is a serious disease that causes high blood pressure, protein in the urine, and oedema, and can result in liver failure, kidney failure and seizures in the mother. It can also lead to restricted growth in the baby and often premature delivery. However, many pregnant women who show symptoms do not have pre-eclampsia. The disease continues to be a poorly understood complication of pregnancy, affecting 2% to 8% of pregnant women worldwide. Women presenting with suspected pre-eclampsia are often tested for a range of common biochemistry analytes, including creatinine, ALT, uric acid and albumin. None of these tests have good diagnostic accuracy for pre-eclampsia and only change late in the developing pathology. Consequently, there has been a large unmet need for more accurate diagnostic tests of this condition.

Markers

One of the biochemical characteristics associated with pre-eclampsia is an imbalance between angiogenic factors, and these factors give good diagnostic accuracy in the detection of the condition. Two proteins are used: placental growth factor (PlGF), which promotes angiogenesis, and soluble fms-like tyrosine kinase-1 (sFlt-1), which inhibits angiogenesis. The markers may be used in two ways: PlGF can be used as a single test, or both markers may be measured to produce an SfLT:PlGF ratio. In Oxford, the latter approach was adopted following an evaluation of the ratio's value in terms of patient outcomes within a clinical study. The ratio has been running in routine clinical practice for a year and applied in a well-defined patient pathway to categorise patients into low risk (SfLT ratio <38), medium risk (ratio 38-85) or high risk (ratio >85). The markers are easy to run on standard automated instruments with good precision, are highly stable, and compare well across different laboratories in sample exchange programmes.

Before the introduction of the new test, almost 70% of patients admitted did not actually have pre-eclampsia and there was no accurate method to determine who would get the disease. Currently, patients with suspected pre-eclampsia are often admitted to hospital, sometimes for several days, in order to make the diagnosis. It is diagnosed by excluding all the other possible causes of high blood pressure and protein in the urine through a series of tests, which take time and cause anxiety for the mother-to-be and her family.

> *The new test helps clinicians make important decisions at a critical stage of pregnancy*

The results of the INSPIRE study, where the tests were evaluated in a real-world routine setting, were reported in the October edition of the journal *Hypertension*. Key findings were the new test's negative predictive value of 99.3% for the following 7 days - meaning improved confidence in discharging patients without pre-eclampsia and the improved safety of mothers with pre-eclampsia. When the test was used it correctly identified 100% of this group compared to 83% with standard clinical practice alone.

The UNIVANTS award is now open for applicants and based on his experience Tim commented: "With the many pressures we have in the NHS laboratory services it is important to not lose sight of the very important developments we can achieve and I would encourage any laboratory who has worked with clinical colleagues on projects of this kind to consider submitting an application." BMS

THE UNIVANTS OF HEALTHCARE EXCELLENCE AWARD

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