Innovation

University Hospitals Dorset NHS Foundation Trust

Placental Growth Factor Test

Med Tech Funding Mandate

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BACKGROUND

Pre-eclampsia is a multisystem hypertensive disorder of pregnancy, thought to be related to problems with the development of the placenta. Approximately 10% of women present with suspected pre-eclampsia between 20 and 34^{+6} weeks of pregnancy, but only 2 – 3 % of all pregnant women will go on to develop pre-eclampsia. Classically the definition for diagnosis has relied on hypertension and proteinuria. However, this method is poor at predicting the clinical onset of the disease and its progression.

If the condition is allowed to progress, it can result in maternal organ failure and foetal growth restriction and in some cases foetal or maternal death. Clinical teams therefore have a high degree of suspicion for the disease and a low threshold to admit pregnant women with suspected pre-eclampsia, placing unnecessary burden on the healthcare system and causing unnecessary anxiety and inconvenience for the woman and her family.

WHAT IS THE INNOVATION

Placental growth factor (PLGF)-based testing is a new blood test providing information on placental biomarkers which, when used alongside other diagnostic and clinical information, can help clinicians to predict, diagnose and appropriately manage potential pre-eclampsia.

Following an extensive consultation process with the Wessex Academic Health Science Network (AHSN), the Elecsys immunoassay sFlt-1/PLGF ratio (Roche) test was introduced at Poole Hospital NHS Foundation Trust in Nov 2019. The sFlt-1/PLGF ratio is a test recommended by the National Institute for Health and Care Excellence (NICE) to help decide on care for women with suspected preterm (20 to 36^{+6} weeks of pregnancy) pre-eclampsia (NICE 2022).

Anticipated benefits of PLGF-based testing include:

- Reassurance to pregnant women with hypertension
- Reduction in the need for unnecessary hospitalisation
- Increased clinical confidence in treatment plans
- Avoidance of emergency medical interventions
- Improved risk assessment to enable early planning for a safe birth
- Facilitation of shared decision making

Published trials examining the clinical effectiveness of PLGF-based testing include the PARROT (Duhig et al 2019), INSPIRE (Cerdeira et al 2019), and PROGNOSIS (Zeisler et al 2016) trials. Within these trials it was found that PLGF-based testing was very useful to help with clinical decision making, reducing the time to clinical confirmation of pre-eclampsia, with a lower incidence of maternal adverse outcomes.

ADOPTION JOURNEY

The timing of the decision to adopt the sFlt-1/PLGF ratio test coincided with a funding call made by the AAC Pathway Transformation Fund (PTF). Through this a grant of £21,000 was successfully secured which supported implementation.

An implementation team was established which included representation from Obstetrics, Maternity, Pathology, Research, Wessex AHSN, and Dorset Innovation Hub. Prior to launch, a number of clinical awareness and training meetings were held. This included updates at the Maternity Obstetrics Steering Group, signing off the pathway through local committees, update to local policy 'Pregnancy Induced Hypertension (PIH) and Pre-eclampsia (PET)', and sessions with the supplier (Roche) for clinical staff.

Activity continues to be complemented by ongoing training via multiple avenues including; monthly mandatory midwife updates, PROMPT (PRactical Obstetric Multi-Professional Training) training, preceptorship training, Facebook and WhatsApp groups.

Adoption of PLGF-based testing was also assisted through the inclusion of PLGF as a supported innovation within NHS England's Innovation and Technology Payment (ITP) programme, and was subsequently also included in the Med Tech Funding Mandate (MTFM) programme. These programmes being designed to support faster and wider adoption of proven, cost-effective innovations by removing financial and procurement barriers.

HOW HAS IT SCALED AND WHAT WERE THE ENABLERS

Since adoption of PLGF-based testing, Poole hospital merged (October 2020) with Royal Bournemouth and Christchurch hospital to create University Hospitals Dorset (UHD). Following this, the PLGF-based test is now also offered to women presenting at the Bournemouth site with suspected pre-eclampsia.

As the PLGF-based test can be utilised as a triage system to aid hospitalisation decisions, it has proved a valuable tool to help minimise hospitalisations during the Covid-19 pandemic. This is evidenced through its recommendation by the Royal College of Obstetrics and Gynaecology in their 'Guidance for maternal medicine services in the coronavirus (COVID-19) pandemic'.

Enablers

- National programmes: AAC PTF, NHSE ITP programme, and MTFM programme
- Involvement of research midwives with experience of adopting new / novel practices
- Presence of senior leadership and support
- Established working relationship between pathology lab and Roche with required equipment already in place
- External technical and training support from Roche and Wessex AHSN
- Training – multiple session run in varied formats with different audiences

KEY CHALLENGES & LEARNING

The introduction of the PLGF-based test represented a new approach to the care of women with suspected pre-eclampsia, and the implementation of any change always presents challenges. These challenges were tackled via several different approaches.

As the PLGF-based test is a novel test, a comprehensive education and training programme was required for all staff working within the service. Thorough knowledge of how to interpret test results and triage patients being key to ensuring continued delivery of safe and effective care.

Training was strongly based within current evidence, including NICE recommendations, and focussed in antenatal day assessment where all women with suspected pre-eclampsia were initially assessed. This developed confidence within the midwifery team in using the test and knowing when to seek guidance and assistance.

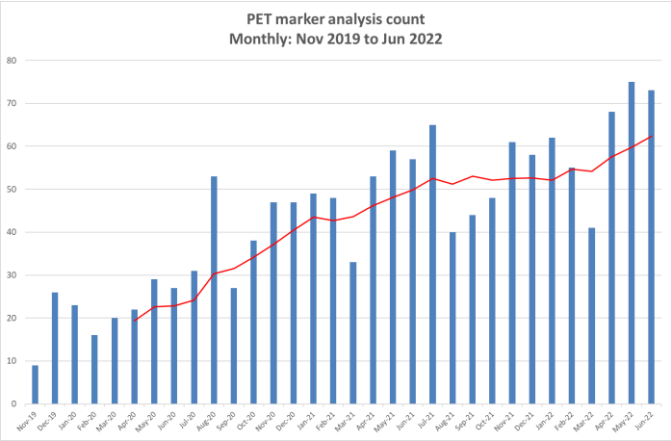
Alongside the sFlt-1/PLGF ratio test, home blood pressure monitoring was also introduced. Having this combination of tools to draw on provided clinicians with confidence to manage women in an outpatient setting, rather than defaulting to unnecessary hospital admissions. Observational outcomes from this include reduction in bed occupancy, less potential exposure to COVID-19 (during peak of the pandemic), better utilisation of staff time / resources, and improved psychological well-being for the women.

The biggest challenge is ensuring sustainability and acceptance of the test as 'business as usual'. One of the key elements will be to ensure that the training programme becomes routine in order to capture rotational staff, new staff, as well as maintaining a level of knowledge which is up-to-date and in line with current guidance.

WHAT WAS THE IMPACT

The antenatal day assessment unit assesses 10 to 15 women per week for various reasons related to hypertension and possible pre-eclampsia toxaemia (PET), equating to approximately 520 to 780 women per year.

It appears that the majority of these women are currently receiving a PLGF-based test, with the rate rising from an average of approximately 20 tests per month during Q4 2019/20 to an average of approximately 52 tests per month during Q4 2021/22.



Local clinical audits have been undertaken in order to review how the PLGF-based test is being used and the outcomes for this cohort of women.

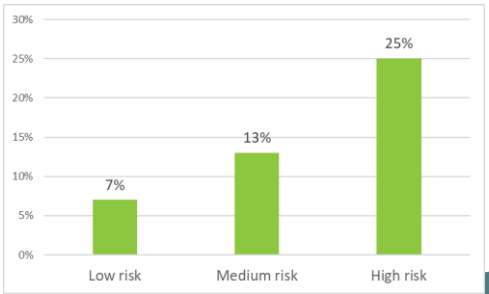
An audit undertaken of 430 referrals for gestational hypertension (Jan to Dec 2020) found that 184 (43%) of the referrals had gone on to receive a PLGF-based test. Following application of exclusion criteria, a subset of 149 of these PLGF cases were reviewed in detail. Within this group (n=149), pre-eclampsia risk categorisation was:

- Low risk = 106 (71%)
- Medium risk = 23 (15%)
- High risk = 16 (11%)
- Not documented = 4 (3%)

Of the 106 low risk cases, 87 (82%) went on to be managed via outpatient care only i.e. no unnecessary hospital admission. Of the 19 low risk cases managed as an inpatient, none had a length of stay which exceeded 48hrs.

Of the 106 low risk cases, 68 (64%) were not prescribed anti-hypertension therapy, with 32 (30%) cases receiving a single anti-hypertension medication, and 6 (6%) cases receiving more than 1 anti-hypertensive medication.

Rate of intrauterine growth restriction diagnosis by PET risk category



A further clinical audit project was undertaken (cohort June to August 2021) to review compliance with NICE guidance in use of the PLGF-based test. Compliance against the audit standards were reported as:

1. Single PLGF-based test only: 71% (27/38)
2. PLGF-based test undertaken in women between 20 and 34^{+6} weeks of pregnancy: 58% (22/38)
3. PLGF-based test undertaken in women with hypertension: 61% (23/38)

NEXT STEPS

- **Benefits realisation**

In order to fully examine the patient benefits from the local adoption of the PLGF-based test, a benefit realisation analysis is planned. It is hoped that this will provide information on the degree to which anticipated benefits, such as reduced inpatient bed days, reduced adverse maternal outcomes, and earlier detection of small for gestation babies, have been seen in practice.

- **Clinical audit**

Alongside the benefits realisation exercise, a further clinical audit is also planned in order to examine current local compliance with practice standards in the use of PLGF-based testing.

- **Training and education**

A continual programme of training and education is required in order to capture new staff and ensure that knowledge remains correct and current. Training and education programmes also help to address potential problem areas in the use of the PLGF-based test e.g. repeat testing.

- **NICE guidance update**

NICE guidance on PLGF-based testing was updated in July 2022, with guidance now recommending using PLGF-based testing as a tool to rule in, as well as rule out, pre-eclampsia. The local implications of this update requires discussion and review.

- **Med Tech Funding Mandate**

Funding for the PLGF-based test is currently covered under the Med Tech Funding Mandate. Pathways have been established to sustain PLGF once this funding ceases.

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