University Hospitals Dorset NHS Foundation Trust

Our Dorset

Placental Group Factor-based Testing

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 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) (now Health Innovation Wessex), 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

Prepared by: Sandra Courtiour
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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 (now Health Innovation Wessex), and the Dorset Innovation Hub. Prior to launch, several 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

Following 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 offered to a wider cohort of women (Poole as well as Bournemouth & Christchurch catchments) with suspected pre-eclampsia.

As the PLGF-based test can be utilised as a triage system to aid hospitalisation decisions, it 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 (now Health Innovation Wessex)
- 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 on 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 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

Since its introduction in November 2019, various data collection exercises have been undertaken to review PLGF test usage and impact, including a prospective data collection exercise at the early stages of implementation to inform an evaluation report as a requirement of the AAC Pathway Transformation funding. More recently, a clinical audit and benefits realisation assessment have been completed (cohort January to March 2022) with a summary of the main results from these presented below.

The number of PlGF-based tests completed has steadily risen since its introduction from an average of approximately 20 tests per month during Q4 2019/20 to an average of approximately 80 tests per month during 2023.

Clinical Audit

A clinical audit of PLGF use and outcomes was completed utilising a sample of 63 cases who had received their first PLGF test during the period 13 January to 31 March 2022 (data collection completed Q1 2023/24).

Characteristics of the sample were:

- Age at time of 1st PLGF test: range 17 to 43 years and average 29.68 years
- 10 (15.9%) cases had experienced PET previously
- 26 (41.3%) cases had PET symptoms at point of 1st PLGF test
- Risk level as per PET ratio (at 1st PLGF test)
    - Low = 47 (75%)
    - Medium = 8 (13%)
    - High = 8 (13%)

Results against the clinical audit standards

Audit criteria	Pass %
PLGF-based testing should be undertaken between 20 weeks and up to 36^{+6} weeks of pregnancy	86% (54/63)
PLGF-based testing should only be undertaken once per episode of suspected preterm eclampsia	86% (54/63)
If PET ratio <38, home BP monitor issued, and at least weekly measurements undertaken	63% (10/16)
If PET ratio 38 to 85 and PCR <30, home BP monitor issued, and at least weekly measurements undertaken	60% (3/5)
If PET ratio 38 to 85 and PCR >30, BP to be measured: 4hrly if inpatient Every 48hrs if outpatient	67% (2/3)
If PET ratio >85, inpatient admission advised, and at least 4hrly BP measurements undertaken	100% (8/8)

Outcomes for clinical audit cohort (n=63)

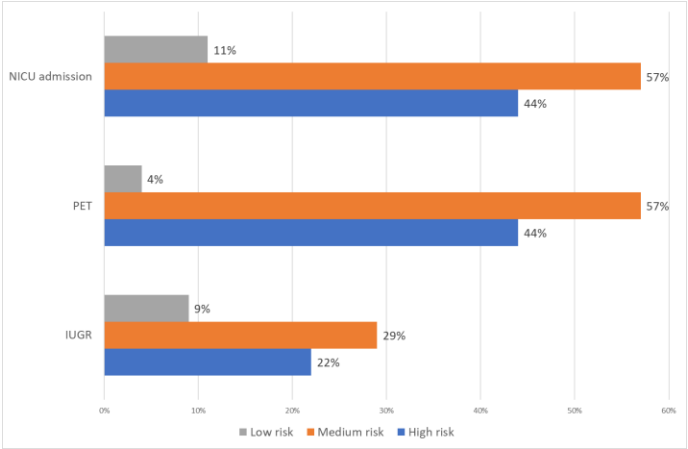
All cases (100%) resulted in a live birth.

Mode of delivery
- Vaginal birth = 24 (38.1%)
- Assisted vaginal birth = 6 (9.5%)
- Caesarean (planned) = 14 (22.2%)
- Caesarean (emergency) = 19 (30.2%)

Gestational baby age at delivery
- <28 weeks = 0 (0%)
- 28 to 31 weeks = 2 (32.%)
- 32 to 37 weeks = 14 (22.2%)
- >37 weeks = 47 (74.6%)

13 (20.6%) babies required an admission to NICU or HDU.

Outcomes by PLGF risk categorisation (at 1st PLGF test) (n=63: Jan to Mar 2022)



NICU – Neonatal Intensive Care Unit. PET – Pre-eclampsia Toxaemia. IUGR – Intrauterine Growth Restriction

Benefits Realisation

As part of the evaluation, a benefits realisation assessment was planned against the key metrics:
- *Benefit 1: Reduction in the rate of inpatient stays due to PET risk*
- *Benefit 2: Reduction in the rate of emergency caesarean section*
- *Benefit 3: Reduction in the rate of severe maternal outcomes*

However, completion of a valid benefits realisation exercise relies on quality pre implementation data to provide a true benchmark. This data was not formally collected pre implementation and was not possible to collect retrospectively due to difficulties identifying 'suspected' pre-eclampsia from coding data and the challenge of manually extracting information from patient notes.

Some pre-implementation data was available via the data generated to inform the AAC Pathway Transformation Fund (PTF) evaluation report but, as this data covers the period Jan to Dec 2020 (Covid pandemic), it was not felt to be representative of true pre implementation clinical practice.

Limitations
It should be recognised and acknowledged that the PlGF test is a single diagnostic tool to be used alongside other diagnostic and clinical information to support clinical decision-making. In a non-research setting, it can therefore not be seen as a sole predictor / causal variable for pathway outcomes of women with suspected pre-eclampsia.

NEXT STEPS

- Review and update of the local (UHD) guidelines 'Pregnancy Induced Hypertension (PIH) and Pre-eclampsia (PET)' to ensure that the following are clearly documented:
    - Amended NICE guidelines (July 2022) to recommend use of the PlGF test to rule in as well as rule out pre-eclampsia.
    - Eligibility criteria for use of PlGF test
    - Single use of test per episode of suspected pre-eclampsia.

- Constant engagement with teaching and training sessions to ensure Obstetrics and maternity unit staff are aware of updates to relevant national and local guidelines.

- Review of availability of home BP monitoring kits to identify if current demand can be met; if not, for appropriate action to be taken to increase the number of available kits.

- Funding to be planned for under normal service provision to enable continuation of the PlGF test once the period of funding under the MTFM policy ceases.

- To undertake a re-audit of local PlGF test usage and outcome in due course.

KEY REFERENCES

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