Rapid implementation of PlGF to support maternity services during the COVID-19 pandemic

Cerys March[1,2], Alexandra Tillett[3], Karin Leslie[4], Balvinder Sagoo[3], Matthew Koomson[2] & Sally Benton[1,2]

1. Berkshire & Surrey Pathology Services (BSPS) 2. Royal Surrey Hospital Foundation Trust, Guildford, UK
3. Frimley Health Foundation Trust, Frimley, UK 4. Ashford & St Peter's Hospital Foundation Trust, Chertsey, UK

Berkshire & Surrey Pathology Services

A joint venture between Ashford and St. Peter's Hospitals NHS Foundation Trust, Frimley Health NHS Foundation Trust Royal Berkshire NHS Foundation Trust and Royal Surrey County Hospital NHS Foundation Trust Legal entity host Frimley Health NHS Foundation Trust

Introduction

Placental Growth Factor (PlGF) is a test that can predict the likelihood of a woman developing pre-eclampsia (PE) and delivering her baby within 14 days (Figure 1). Current PE diagnosis is subjective, and many women are admitted to hospital for unnecessary monitoring. This is unwelcome, especially considering the Covid-19 pandemic where any hospital visit/stay puts the patient at risk of contracting the virus. In 2016 PlGF was recommended by NICE (DG23) yet this had not been implemented within Berkshire & Surrey Pathology Services (BSPS), which covers five acute hospitals. Two different methods for PlGF are recommended: Quidel Triage PlGF or the Roche PlGF/sFlt-1 ratio.

Here we report the rapid implementation of a PlGF testing service across four acute hospitals, to support maternity services during the Covid-19 pandemic.

Clinical contact

In April 2020 maternity teams at five hospital sites covered by BSPS were contacted via email to ask if PlGF would be considered valuable to their services. Four sites responded positively: St Peter's Hospital, Wexham Park Hospital, Frimley Park Hospital and Royal Surrey Hospital.

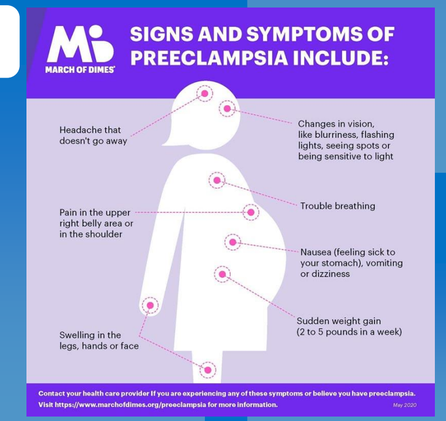

Figure 1: Signs and symptoms of preeclampsia. From: https://www.marchofdimes.org/complications/preeclampsia.aspx

Choice of assay

An options appraisal confirmed the Quidel PlGF method was the best fit for BSPS due to its small, low-cost analysers and simple assay allowing short turnaround times and good contingency across the multiple sites. Roche analysers were not available on all sites. The assay would be based in the laboratory because centrifugation was required.

Figure 2: The Quidel Triage MeterPro analyser. From: Quidel.com

Validation

An analytical validation of four Triage MeterPros (Figure 2) was carried out. Within day imprecision was assessed by analysing two internal quality control (IQC) samples 5 times on a single day. Between day imprecision was assessed by analysing two IQC samples once a day over 5 days. To assess between analyser accuracy, 9 anonymised plasma samples from pregnant women were and used as positive samples. One anonymised plasma sample from a male patient was used as a negative control and six UKNEQAS samples were examined on each of the four analysers.

Clinical pathway

The clinical teams across the network generated clinical pathways for pregnancy-induced hyper-tension to align to the Quidel method.

Results

Within and between batch imprecision for the Triage MeterPro was 7.4% to 18% (within manufacturer quoted ranges). The patient comparisons showed very good agreement between the four analysers with mean bias between them of 2% to -2%.

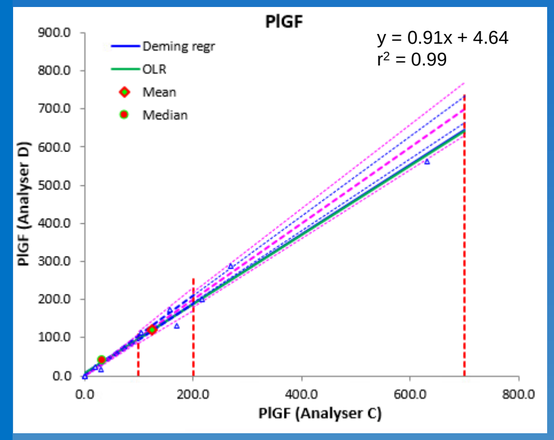

Figure 3: Example comparison of two Triage MeterPro Analysers running PlGF

EQA results were also encouraging with all results within 1 SD of the all lab trimmed mean. The service went live on 1st June 2020, just 6 weeks in to the project.

Between 1st June and 31st December 2020 322 samples from 264 women were analysed (Figure 4). 306 samples (95%) had a result reported within our stated turnaround time of 4 hours.

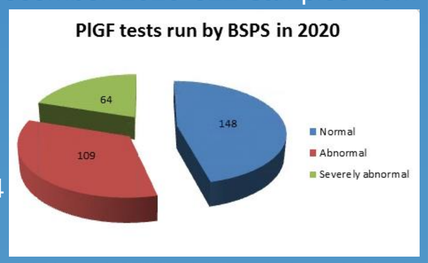

Figure 4: PlGF results from BSPS in 2020. Normal: >100 pg/ml, Abnormal: 12-99.9 pg/ml, Severely abnormal: <12 pg/ml.

Discussion

We rapidly implemented the PlGF test on Quidel. This has been well used by our service and we are in the process of carrying out a clinical audit to assess clinical utility of the test.