

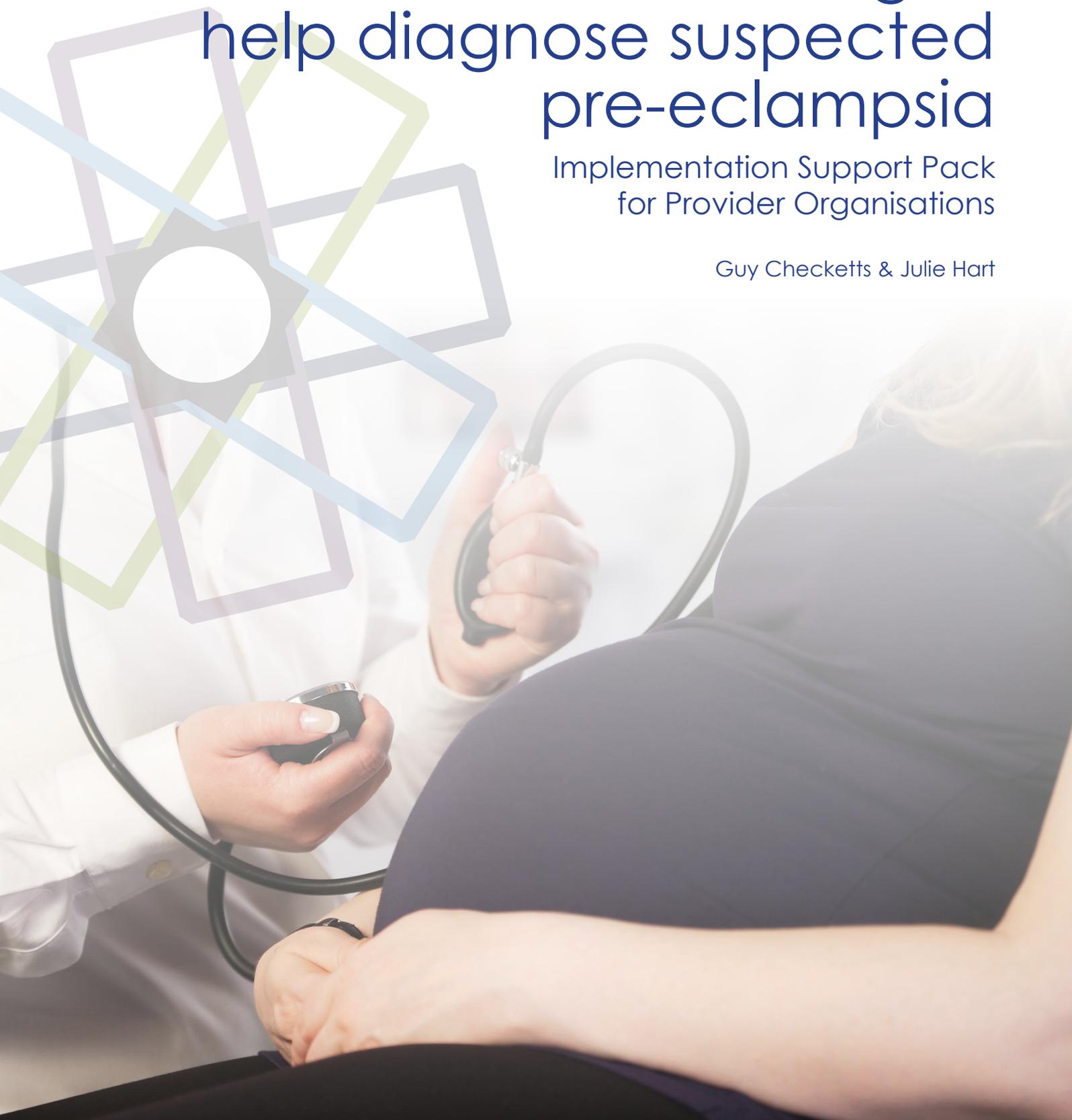
NICE Implementation
Collaborative Project

Oxford 
Academic Health
Science Network

PIGF-based testing to help diagnose suspected pre-eclampsia

Implementation Support Pack
for Provider Organisations

Guy Checketts & Julie Hart



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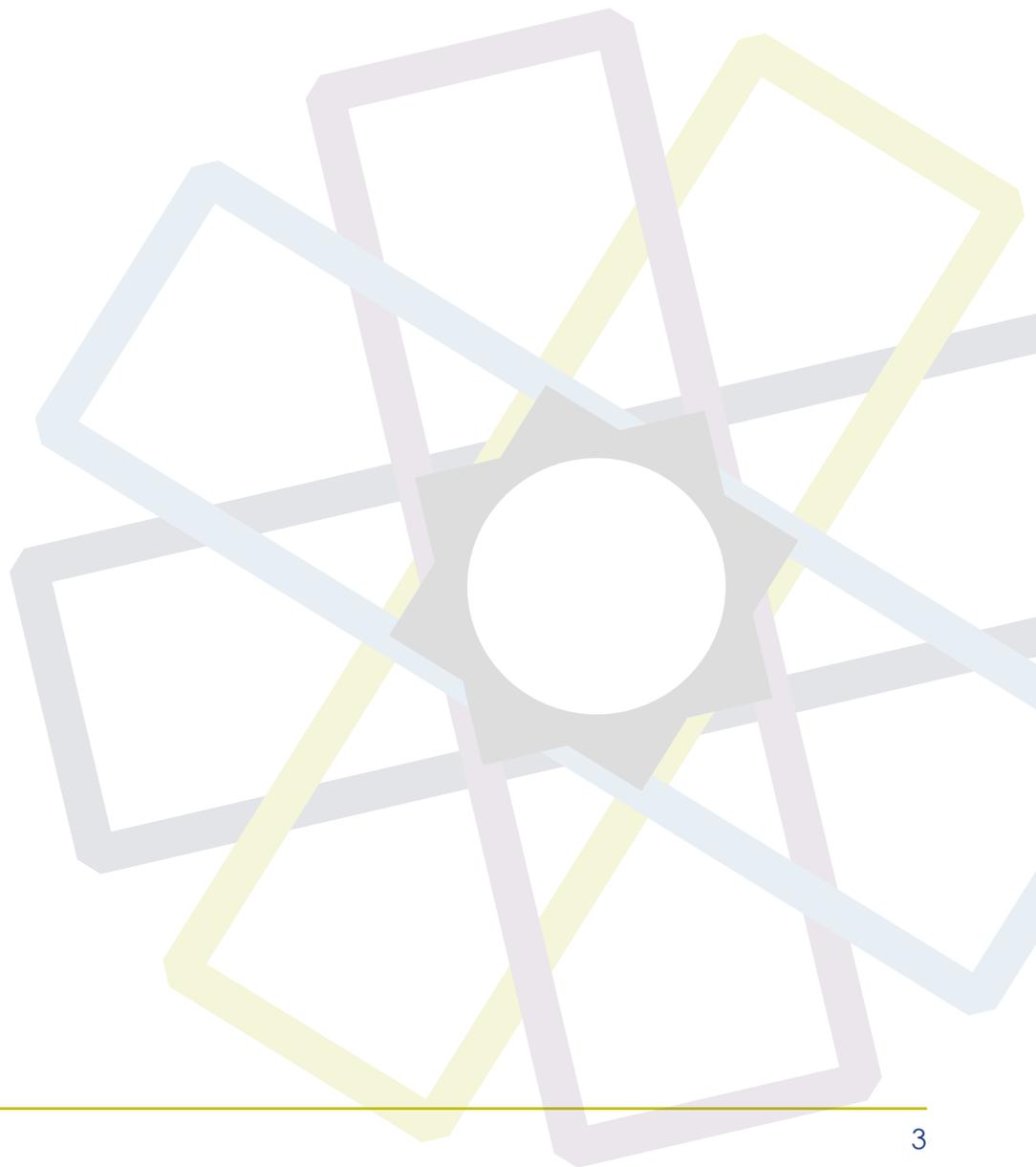
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Introduction

This **Implementation Support Pack** has been compiled by Oxford Academic Health Science Network (Oxford AHSN) for the NICE Implementation Collaborative (NIC). The NIC is a partnership between the NHS, the life sciences industry, healthcare professional bodies and key health organisations who have committed to work with each other to understand and analyse the barriers that exist to the implementation of NICE recommendations.

This pack aims to provide Trusts with all the necessary information to implement this product, providing clinicians and project leads with a step-by-step guide of how to implement Placental Growth Factor (PlGF)-based diagnostic testing for suspected pre-eclampsia. The pack includes a number of resources to help simplify the process of implementation and advice on how to handle challenges to adoption and overcome potential barriers to implementation.

The guidance in this document is based on the experiences in three trusts in the Oxford AHSN region. Differences in practice, protocols and systems at different Trusts may mean that processes vary slightly. If this is the case, please do share these differences with contacts at the Oxford AHSN for future learning and to help other partner organisations.



Summary overview

PIGF-based diagnostic testing helps with risk stratification of women with suspected pre-eclampsia (PE) and to help keep the woman on the standard antenatal care pathway.

Benefits of PIGF-based testing:

- “Rule out” PE - the woman can be kept on the standard care pathway
 - o Reduces pressure on capacity and fixed resources
 - o Positive impact on the woman and her family from not being admitted (unnecessarily)
 - o Avoids (unnecessarily) moving the woman onto a more intensive care pathway, putting demand on scarce resources and finances
- “Rule in” PE - the woman can be “knowingly” and appropriately treated for PE, delivering patient-safety benefits
- Identify real-world “cash-releasing” cost savings based on appropriate stratification of women with / without PE

Key points

Pre-eclampsia is a multisystem hypertensive disorder of pregnancy that affects approximately 3% of all pregnancies (approximately 23,000 cases per year in the UK), however to date there has been no definitive test to help diagnose PE. The exact cause of the condition is unknown, but it is thought to occur when there is a problem with the placenta (the placenta becomes dysfunctional or “unwell”) and the only way to cure PE is to deliver the baby.

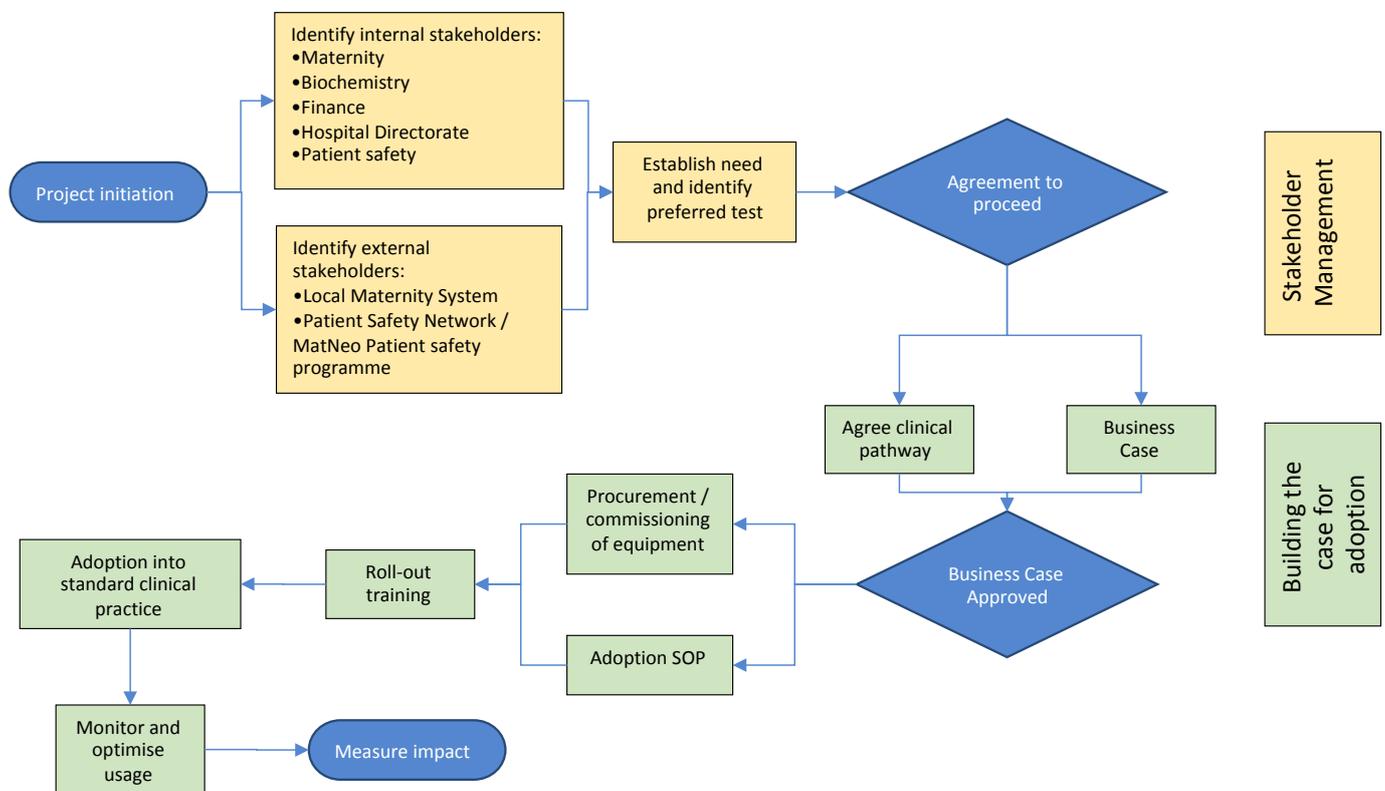
PE is a serious condition and is a significant cause of maternal and foetal morbidity in the UK and one of the leading causes of maternal and foetal mortality worldwide. Early signs of PE include having high blood pressure (hypertension) and protein in the urine (proteinuria). If the disease is allowed to progress, it can result in maternal organ failure and foetal growth restriction, early induction and in some cases foetal or maternal death.

In view of these poor outcomes and the impact on women and their families, clinical teams have a high degree of suspicion for the disease and a low threshold to admit pregnant women with suspected PE. However, hypertension and proteinuria are not specifically characteristic to PE; 10% of women in pregnancy may have some form of hypertension and proteinuria. Indeed, the positive predictive value for hypertension and proteinuria predicting an adverse outcome is only 20% (Zhang et al 2001 *Obstetrics & Gynaecology* 97 261-7).

Unfortunately, both hypertension and proteinuria are sub-optimal predictors of which women will develop PE and how the disease will progress. Consequently, many women with signs and symptoms of the disease are either admitted to hospital for intensive observation and monitoring unnecessarily (resulting in worry for them and their families and additional costs to the health provider), or alternatively there is a delay in appropriate care being delivered due to diagnostic uncertainty placing both mother and baby at increased and unnecessary risk.

Overview of the implementation process

Below is a suggested outline process for the adoption of PIGF-based testing for suspected PE, that has been developed based on the experience of trusts that have worked with Oxford AHSN to date. The process is made up of two core elements: stakeholder engagement and building the case for adoption, followed by approval and adoption of the test into clinical practice.



Step 1: Identify internal stakeholders

Internal project stakeholders are likely to include:

- Maternity consultants (OB-GYN)
- Midwives and nurses
- Biochemistry lab management and staff / Point of Care Committee
- Maternity and / or Hospital Finance
- Medical Directorate / Hospital Management
- Human Resources
- The Trust's Patient Safety Board Leads
- Local AHSN / Patient Safety Network

External stakeholders can be very useful in driving the case for adoption from a patient safety angle under national or local initiatives, and could include:

- Local Maternity System
- Accelerated Access Collaborative / Innovation Technology Payment
- Charities e.g. Action on Pre-eclampsia Charity (APEC)

Project delivery by Oxford AHSN was driven through the Oxford Maternity Patient Safety Network, to which all the partner hospitals belonged. This provided a very useful vehicle to help with alignment to a common goal in adopting PIGF-based testing and to ensure a common understanding and vernacular. The communication strategy should align the benefits of PIGF-based testing to the relevant stakeholder, for example:

Stakeholder	Message
Clinical	<ul style="list-style-type: none"> • Risk reduction • Increased support for clinical decision making • Improved clinical management of women and their babies • Maintenance of most appropriate antenatal care pathway • Fewer early interventions due to a suspicion of PE • Safely send woman home if PE excluded • Appropriate clinical intervention for positive diagnosis • Improved patient safety and outcomes • More appropriate admissions and use of bed days • Improvements in capacity and resource management
Labs	<ul style="list-style-type: none"> • Risk reduction • Increased support for clinical decision making • Improved patient safety and outcomes • Improvements in capacity and resource management
Finance / management	<ul style="list-style-type: none"> • Risk reduction • Improved patient safety and outcomes • More efficient use of scarce resources • Cost savings based on reduced admissions, monitoring and providing unnecessary care for those women who do not have PE • Reduced costs associated with pre-term deliveries and subsequent neonatal care
Patient safety organisations	<ul style="list-style-type: none"> • Improved clinical management of women and their babies • Risk reduction • Increased support for clinical decision making • Improved patient safety and outcomes • Improvements in capacity and resource management

It has been found that the most effective means of securing buy-in, agreement to proceed and completing actions in a timely fashion is to hold face-to-face meetings with all decision-making stakeholders in attendance. The absence of any one function will derail common agreement and successful progress.

Step 2: Identify preferred test

In May 2016, NICE published its guidance document on the use of PIGF-based testing to help diagnose suspected pre-eclampsia, NICE Guidelines DG23.

Two diagnostic tests introduced by Roche Diagnostics (the Elecsys sFlt-1/PIGF ratio test) and Quidel Corporation (the Quidel Triage PIGF test) provide the ability to better diagnose suspected PE and to assess the risk for complications associated with PE. As such they offer clinical teams the ability to better manage risk and provide appropriate care to the woman and her unborn baby. The tests not only prevent unwarranted admissions for the suspicion of PE but also allow for an appropriate regimen of planned care to be delivered for these women if a diagnosis is made. This reduces the burden on the system (financial, capacity) improving both patient safety and patient outcomes, which is beneficial for women, their families and the maternity service.

Roche Diagnostics - Elecsys sFlt-1/PIGF ratio test: The Elecsys ratio test measures two circulating placentally derived biomarkers; soluble FMS like Tyrosine kinase 1 (sFlt-1) and Placental Growth Factor (PIGF). These biomarkers are detectable in the circulation of pregnant women and their levels are altered in PE; sFlt-1 becomes elevated and PIGF is decreased.

With the Elecsys test, the levels of sFlt-1 and PIGF are measured then converted into a ratio which can predict the women who will NOT get PE in the following seven days. The Elecsys test can be run on any Roche Elecsys or Cobas e automated analyser in a lab environment.

Quidel Corporation – Quidel Triage PIGF test: The Quidel Triage PIGF test is a quantitative immunoassay for the measurement of PIGF. Circulating maternal PIGF levels are abnormally low in pregnancies with defective placentation and the test is used to help detect abnormal placentation in pregnancies where there is clinical suspicion of preterm PE. PIGF helps clinicians and midwives to accurately diagnose PE and to assess the risk for complications associated with PE.

The Quidel Triage PIGF test is run on the Triage MetroPro analyser. It is positioned as either a point-of-care or lab-based test.

It is recommended that the Trust meet with both manufacturers to determine which test is most appropriate in meeting their needs.



Roche Elecsys e411 Analyser



Quidel MeterPro Analyser

Step 3: Agree Clinical Pathway

The lack of widespread adoption of NICE guidance DG23 underpins the AHSN Network's ambition to drive the uptake of PIGF-based testing to help diagnose suspected PE to improve patient safety and to deliver benefits to the healthcare system.

NICE DG23 recommends that a diagnostic test is used, with standard clinical assessment and subsequent clinical follow-up, to help rule out PE in women presenting with suspected PE between 20 weeks and 34 weeks plus 6 days of gestation.

The DG23 resource impact model that accompanies these guidelines is very useful for initial discussions and in understanding the numbers of women involved, the appropriate clinical pathway and the impact of introducing the test.

		sFlt-1/PIGF ratio	
Aid in diagnosis of preeclampsia	20 weeks to 33 weeks plus 6 days	Rule-out cut-off	33
		Rule-in cut-off	85
	34 weeks to delivery	Rule-out cut-off	33
		Rule-in cut-off	110
Short term prediction of preeclampsia (24 weeks to 36 weeks + 6 days)		Rule-out*	<38

Table 1: Recommended cut-off values for the **Elecsys immunoassay sFlt-1/PIGF ratio test**

Result	Classification	Interpretation
PIGF <12pg/ml	Test positive – highly abnormal	Highly abnormal and suggestive of patients with severe placental dysfunction and at increased risk for preterm delivery
PIGF ≥12 pg/ml and <100 pg/ml	Test positive – abnormal	Abnormal and suggestive of patients with placental dysfunction and at increased risk for preterm delivery
PIGF ≥100 pg/ml	Test negative – normal	Normal and suggestive of patients without placental dysfunction and unlikely to progress to delivery within 14 days of the test

Abbreviations: PIGF, placental growth factor; pg/ml, picograms per millilitre

Table 2: Recommended cut-off values for the **Quidel Triage PIGF test**

A PE pathway was developed by the Oxford Maternity Patient Safety Network based on the Elecsys sFlt-1/PIGF ratio test and was approved for use by member hospitals. A second PE pathway for use with the Quidel Traige PIGF test as a Point of Care (POC) pathway has been developed by Leeds Teaching Hospitals NHS Trust. Both of these pathways are shown at the end of this document.

IT SHOULD BE MADE EXPRESSLY CLEAR TO USERS WHICH MANUFACTURER'S TEST IS BEING ADOPTED AND THE SPECIFIC PATHWAY THAT IS BEING FOLLOWED, AS THE CUT-OFFS FOR THE TWO ASSAYS ARE NOT INTERCHANGABLE.

Step 4: Business case approval

The DG23 guidance is written with the use of the PIGF test providing a "rule-out" i.e. use of the test is intended to eliminate the diagnosis of PE and hence reduce the number of (unnecessary) admissions. It should be noted in real-world use that either test also forms a strong "rule-in" where PE is confirmed or when placental dysfunction is suggested. This leads to strong patient safety implications as intervention can be made for those women identified as having PE and who therefore need urgent care where there was previously diagnostic uncertainty.

The DG23 resource impact model is limited in that it only compares the cost of implementing the PE test against the reduction in the numbers of admissions made for suspected PE. Through the work undertaken by Oxford AHSN this model has been shown not to be representative of the "real-world", where a reduction in admissions only becomes tangible for finance functions at a level where enough savings are made for that hospital to reduce capacity by closing wards or reducing headcount. If the real-world impact of the test is required, the direct costs associated with e.g. admissions and subsequent follow-up for suspected PE, the cost associated with premature deliveries and neo-natal care, etc, must be quantified for each Trust according to their local pathways and cost structure.

By way of an example, figures calculated from the Oxford "real world" data and has been shown to be more cost effective than using the NICE resource impact template alone (-£225,111).

Adopting the Elecsys sFlt-1/PIGF ratio test into routine clinical practice in the Oxford AHSN region is predicted to Lead to savings of approximately £342,000 and prevent 1,813 admissions.

The cost model for Oxford is made using various assumptions about the full-loaded cost of running the Roche Elecsys ratio test and is intended as an example only, as the situation within each Trust may be markedly different.

In conducting any local cost / impact assessment, various factors should be considered in determining the true local cost to the system:

- Cost of acquiring, installing, training on and maintaining the relevant analyser
- List price of reagents
- Local discounts negotiated by the Trust with the manufacturer
- The number of "reportable" tests expected to be undertaken each year and the QC regimen established by the labs
- On-costs for each test in addition to the base cost of the reagents

Step 5: Procurement / commissioning of equipment

Once there is agreement from clinical, lab and managerial teams to proceed, implementation leads will need to work with procurement and finance. Reagents will be available from April 2019 under the Innovation Technology Payment (ITP). It should be noted that under the ITP scheme, only the cost of the reagents will be paid for. The Trust will need to fund the cost of any capital and all overheads during the ITP window from local funds and prove the benefit of PE testing via business case to secure on going funding once ITP payments cease.

Support is available from the manufacturers for the provision, installation commissioning and training on the relevant analyser.

Step 6: Roll-out training

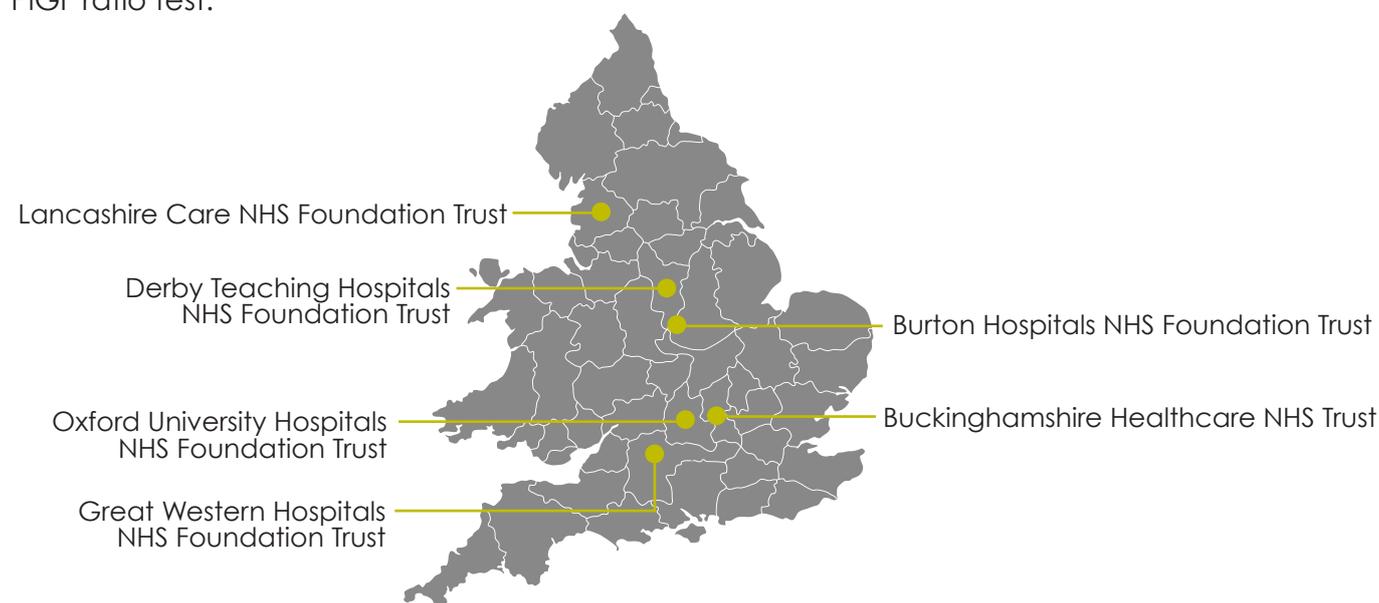
Education and awareness raising is crucial for implementing PIGF-based testing safely. Education efforts should target midwives and doctors working in maternity assessment units or wards, and community midwifery teams. Outreach can take the form of presentations at team meetings, junior doctor inductions, study days, specific training sessions, and targeted emailing to appropriate staff. Two particularly important areas to include are:

- The length of time the result is valid, which is 14 days using the Triage PIGF test, and seven days (rule out) using the Elecsys sFlt-1/PIGF ratio.
- The decision to deliver; local services will need to ensure that the staff responsible for making the decision for early delivery have enough experience and knowledge of preterm pre-eclampsia to guide the decision-making process. This decision should be based on clinical judgment, not PIGF-based testing alone. Furthermore, sufficient lab staff must be trained on the analyser to provide adequate coverage for the agreed service level.

Step 7: Adoption into practice

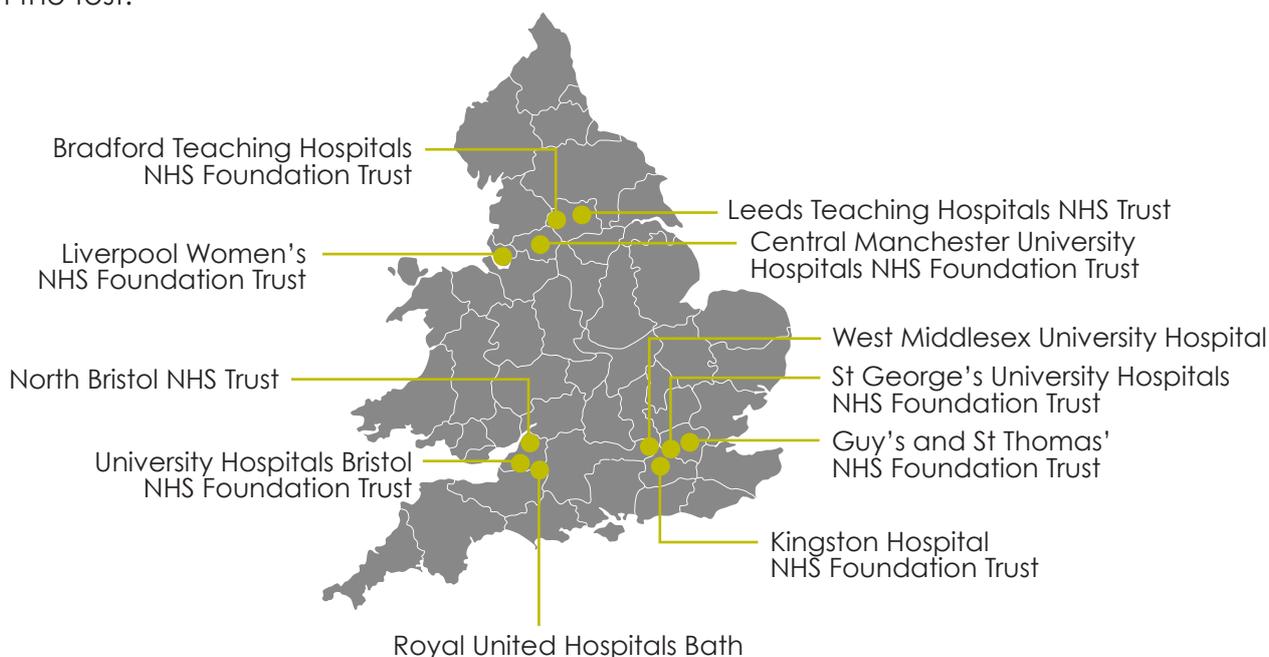
Once training has been delivered and stock has been received, leads should look to introduce PIGF-based testing into practice. Specifying a date at which PIGF-based testing will be available would provide a defined timeframe for staff to become accustomed to the new practice.

At the time of writing (July 2019), the following NHS Trusts have adopted the Roche Elecsys sFlt-1/PIGF ratio test.



Once fully adopted, it is envisioned that the test can be requested and acted on by both consultants and midwives alike to facilitate utility of the test, although during the adoption period it seems that it is the consultants who are making the decision to act based on the test results in conjunction with the broader assessment of the woman. Ongoing analysis is examining the uptake and degree of penetration across the maternity service as well as the effects of coverage and availability during the adoption period.

The Quidel Triage PIGF test has been used in the following sites as part of the PARROT trial, therefore the relevant AHSN should seek to engage with these sites first who are already familiar with the test:



Step 8: Monitor and optimise usage

Tracking metrics and analysing the impact of PIGF-based testing for suspected PE has proved to be challenging so far due to coding peculiarities and the manual nature of much of the record keeping, which hampers data searching.

Following the intent of DG23, the simplest metric to consider is the number of admissions for suspicion of PE before and after the introduction of the diagnostic PIGF test. It should be noted that there is no code for "suspected pre-eclampsia" therefore identifying the reason why an admission was made may not be straightforward and as previously discussed, the number of overall admissions following test introduction may not dramatically reduce.

A high-level picture of overall activity and numbers presenting could be built up from an audit of e.g. the attendance register from MAU / DAU, but this may well be a very manual process. To achieve a greater level of detail an analysis of clinical histories will need to be made, however this will likely require a manual audit of patient records.

Fortunately, understanding the numbers of PIGF and other relevant diagnostic tests requested, with associated results and dates, is much easier through automated interrogation of the labs data systems.

The following list illustrates the metrics being tracked at hospitals supported by Oxford AHSN that have adopted PIGF-based testing:

- Total pregnancies and presentations at MAU / DAU
- Proportion of women that present with suspected PE
- Proportion of women with suspected PE that are tested
- Proportion of women who have PE ruled out after testing and clinical assessment
- Rates of retesting for PIGF
- Rates of admission for monitoring suspected pre-eclampsia, with associated treatment
- Rates of admission for confirmed cases of pre-eclampsia, with associated treatment
- Mean duration of hospital stay following admission, pre- and post-adoption of the test
- Outcomes for women with suspected / diagnosed pre-eclampsia
- Early delivery / mode of delivery
- Uptake of the PIGF test over time, including coverage and availability (adoption curve)

It should be noted that there are specific reporting requirements to NHSE for any Trust adopting PIGF testing under the ITP funding programme. Details of these reporting requirement can be found in the NHS England Innovation and Technology Payment Notes, available through your local AHSN.

Potential Barriers to Implementation and Mitigating Action

Implementation of innovation is rarely straightforward and in many cases barriers and challenges faced at one Trust will be similar to those experienced at other Trusts. Key learning from the journey to adoption and implementation of PIGF-based testing in the Oxford AHSN region has been to first identify and then secure the buy-in of the multiple stakeholders that the project will have.

Stakeholders will include the maternity service (consultants and midwives, mainly in the hospital but also potentially in the community once adoption spreads), the hospital biochemistry labs who will run the test, finance (either maternity and / or hospital finance), patient safety representatives (the hospital should have a Board level patient safety representative), Human Resources, clinical directorate, the broader hospital management and organisations responsible for improving maternity services such as the Local Maternity System (LMS).

It has universally been the case that all stakeholders, once identified and engaged, have very quickly acknowledged the benefit of PIGF-based testing at a purely "intellectual" level. The challenge has come in achieving alignment across the different functions to implement and adopt the test, as they are very likely each to have very different drivers and priorities (and their budgets will likely be siloed and therefore unaligned).

For the **maternity service** itself, once the clinical evidence is understood and accepted the benefit of adopting PIGF-based testing is immediately clear; women will receive a more accurate and quicker diagnosis of having pre-eclampsia (or not). The maternity service will be able to deliver more appropriate care by allowing women to go home or admitting them to hospital for observation or intervention more appropriately, to improve outcomes and make better use of scarce resources. Patient safety representatives will (should) also have a strong driver to adopt of the test.

The **lab service** is likely to be the most adversely impacted by the introduction of a new test, depending on how they are staffed and funded, and hence is most likely to be the biggest “blocker” to adoption. If they do not already have an appropriate analyser available, the labs will be asked to acquire, install and maintain new equipment and to train staff in its use. It is also possible that the diagnostic test could be the only one run on the analyser, which will have an adverse impact on the lab's efficiency and cost of running the test. The cost per PE test should also be determined, as running a low volume of reportable tests is likely to give a higher cost per test than a higher volume.

Finance and management functions will be focused on the financial implications of introducing the new test. If taken at a purely local level, it could easily be perceived that the cost of implementing PIGF-based testing is not viable due to the (potentially) high cost per reportable test. Financial stakeholders should be sought at the appropriate level where the benefits of delivering an improved clinical service, patient outcomes and reduced impact on neo-natal care costs makes sense in the context of the direct cost incurred in running the test.

The Trust must decide which test it wishes to adopt. As discussed previously, the two tests do not measure the same parameters nor give the same clinical outcome: The Roche Elecsys sFlt-1/PIGF ratio test gives a prediction of the chances of the woman having or developing PE in the next 1-4 weeks, whereas the Quidel Triage PIGF test gives an indication of the health of the placenta and the risk of delivery in stated timeframes. Other factors such as available lab space and an incumbent lab provider may also need to be considered.

If the case cannot be made to place an analyser locally, it may be appropriate to use an existing lab network and adopt a remote diagnostic pathway.

Resources

- <https://www.nice.org.uk/guidance/dg23> **DG23 NICE PIGF-based testing to help diagnose suspected pre-eclampsia guidelines**
- <https://www.nice.org.uk/guidance/dg23/resources/resource-impact-template-excel-2484575821> **DG23 Resource impact model**
- <https://www.nice.org.uk/guidance/ng133> **NG133 NICE Hypertension pregnancy guidelines**
- <https://drive.google.com/file/d/1pm39SnwA8LEM4cXUw7vX14eUXSYndRZd/view?ts=5b7177f5&pli=1> **Patient video produced by Roche Diagnostics**
- https://drive.google.com/file/u/0/d/1K_EfL6CPEGH9CpEpv6r1fvqIY_GTV_2Y/view?usp=sharing_eil&ts=5b7177a2&pli=1 **Clinician video produced by Roche Diagnostics**
- <https://www.quidel.com/immunoassays/triage-test-kits/triage-plgf-test> **Quidel Triage PIGF test**
- <https://diagnostics.roche.com/global/en/products/params/electsys-sflt-1-plgf-pre-eclampsia.html> **Roche Sflt-1/PIGF ratio test**
- <https://www.england.nhs.uk/wp-content/uploads/2016/02/national-maternity-review-report.pdf> **National Maternity Review Report - Better Births**

References: Roche Elecsys sFlt-1/PIGF Ratio Test

- Predictive Value of the sFlt-1/PIGF Ratio in Women with Suspected Pre-eclampsia (PROGNOSIS Trial). Zeisler et al 2016 N Eng J Med **7;374** 13-22
- INSPIRE Trial. Awaiting publication

References: Quidel Triage PIGF test

- Chappell, LC. Diagnostic accuracy of placental growth factor in women with suspected pre-eclampsia: a prospective multicentre study. *Circulation*. 2013 Nov 5;128(19):2121-31.
- The PARROT Study. Placental growth factor to Assess and diagnose hypertensive pregnant women: a stepped wedge randomised controlled trial. Duhig et al. Published Online April 1, 2019 [http://dx.doi.org/10.1016/S0140-6736\(18\)33212-4](http://dx.doi.org/10.1016/S0140-6736(18)33212-4)
- Duckworth, S. Placental Growth Factor (PLGF) in Women with Suspected Pre-Eclampsia Prior to 35 Weeks' Gestation: A Budget Impact Analysis. *PLoS One*. 2016 Oct 14;11(10).

General references

- Levine RJ et al. N Eng J Med 12:350 672-83 (sFlt-1/PIGF as biomarkers)
- Zhang et al 2001 *Obstetrics & Gynaecology* 97 261-7 (indicators of PE)
- Clinical characterization and outcomes of pre-eclampsia with normal angiogenic profile. Rana et al. <https://www.tandfonline.com/doi/full/10.3109/10641955.2013.784788>
- Pregnancy Hypertension: An Intl Journal of Women's Cardiovascular Health 2; 175-239.

Costs and manufacturer contacts

Roche Diagnostics: Roche ELECSYS Ratio Test

- Analyser: Roche have committed to place the analyser free of charge under the ITP/AAC programme
- Elecsys sFit-1 reagent (100 test) 05109523190 List Price: £3117.96 + VAT
- Elecsys PIGF reagent (100 test) 05144671190 List Price: £3117.96 + VAT

NB. **Both** reagents are required to run the ratio test

Roche Diagnostics, Charles Ave, Burgess Hill, RH15 9RY, UK www.roche.co.uk

Contact specifically for PIGF-related enquiries burgesshill.accessinnovation@roche.com

Contact: Julia Eades julia.eades@roche.com

Tel: 07948 613057

Office: 01444 256000

Quidel Corporation: Quidel Triage PIGF Test

- Triage MeterPro – 55071. Hettich centrifuge – EBA 20. Quidel have committed to place the analyser and centrifuge free of charge under the ITP/AAC programme
- Service contract – £259 + VAT (per year)
- PIGF Control 1 kit - 98813EU (contains 5 vials, each sufficient for one QC test); List price £100 + VAT
- PIGF Control 2 kit 98814EU (contains 5 vials, each sufficient for one QC test); £100 + VAT
- Triage PIGF device kit 98800EU (each contains 25 tests); £1,750 + VAT

AHSN, AAC, or ITP enquiries: Nigel Thomas 07557 519003

Customer enquiries: Monday-Friday from 7:30 AM (07:30) to 5:00 PM (17:00) (GMT +1/Summer, GMT/Winter)

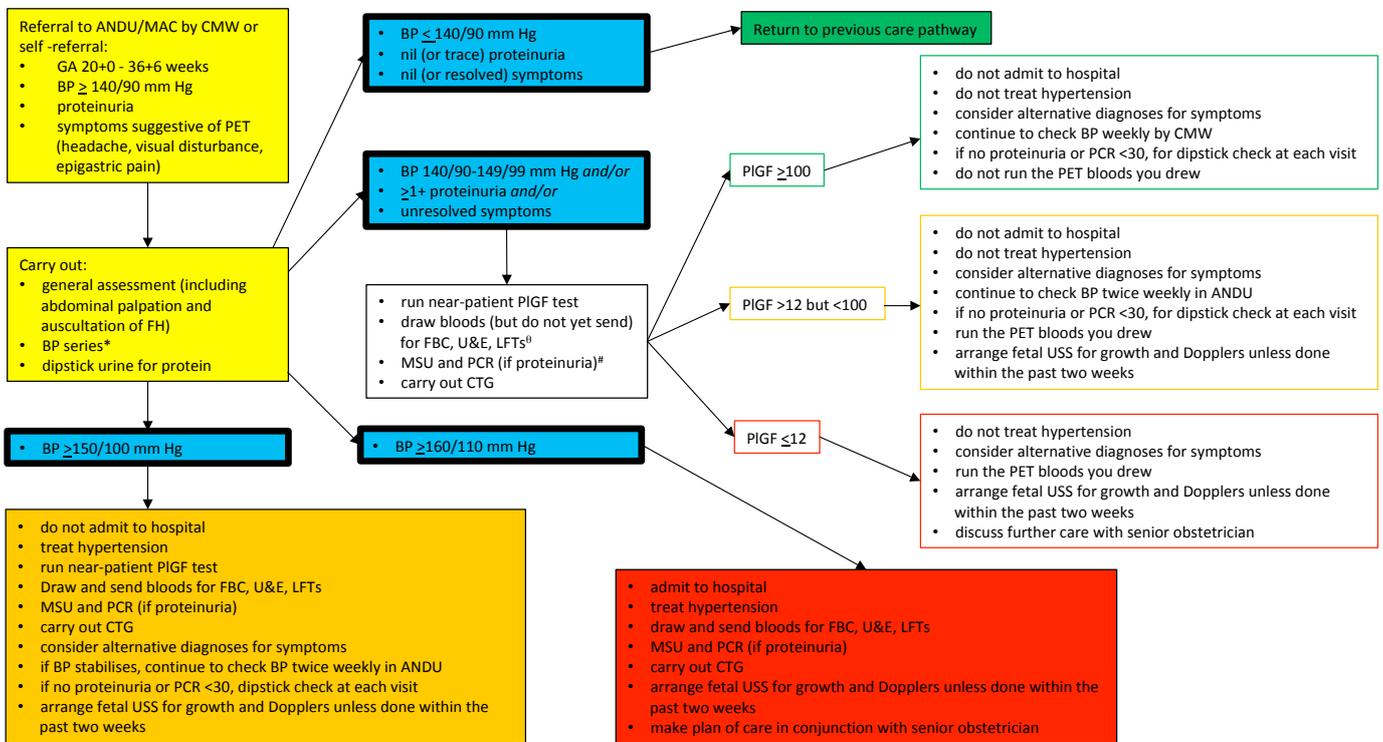
Tel: +44 (800) 3688248 (Option 1 for Customer Service)

Web: <https://www.quidel.com/support/customer-support>

E-mail: emeacustomerservice@quidel.com

Clinical pathway / algorithm – Quidel Triage PIGF

The following pathway has been created by the Leeds Teaching Hospitals NHS Foundation Trust, for use of the Quidel Triage PIGF test as a POC test in the management of suspected pre-eclampsia



*Take three blood pressure recordings at least 10 minutes apart; if the first two readings are both less than 140mmHg systolic and 90mmHg diastolic the third reading can be omitted; from these multiple readings, calculate the average systolic and diastolic reading

[§]Only send coagulation screen if LFTs abnormal; do not request urate

[#]if any PCR result is greater than 30, regard as proteinuric and do not repeat

Example business case initiation proposal

Faster and more accurate diagnosis of pre-eclampsia (PE) leading to better outcomes for women with suspected PE

Date

Lead Clinician	
Other stakeholders	
Function	Name and Title
Brief Description of Proposal	
Implementation of PIGF-based testing for suspected pre-eclampsia thereby reducing unnecessary admissions to the Maternity Unit and improving patient safety	
<p>What is the issue that is being addressed? What will the benefits of the proposal be?</p>	
<p>Pre-eclampsia (PE) is a multisystem hypertensive disorder of pregnancy that affects approximately 3% of all pregnancies, however to date there has been no definitive test to help diagnose PE. The exact cause of the condition is unknown, but it is thought to occur when there is a problem with the placenta and the only way to cure pre-eclampsia is to deliver the baby. It is a serious condition and is a significant cause of maternal and foetal morbidity in the UK and one of the leading causes of maternal and foetal mortality worldwide. In view of these poor outcomes and the impact on women and their families, clinical teams have a high degree of suspicion for the disease and a low threshold to admit pregnant women with suspected PE. Early signs of PE include having high blood pressure (hypertension) and protein in the urine (proteinuria) but these symptoms are not specifically characteristic to this condition; 10% of women in pregnancy may have some form of hypertension and proteinuria. Indeed, the positive predictive value for hypertension and proteinuria predicting an adverse outcome is only 20% (Zhang et al 2001 Obstetrics & Gynaecology 97 261-7). This means that many women are admitted when very few actually go on to develop PE.</p> <p>Diagnosing PE</p> <p><i>Add description of the preferred diagnostic test here (Roche or Quidel) including clinical evidence and pathway based on the respective cut-offs</i></p> <p>Include any commentary relating to the local situation for example</p> <ul style="list-style-type: none"> • Historical levels for PE or hypertensive disorders • Number of admissions for PE • Changing birth rate • Local patient safety drivers • Cost saving drivers • Identified local benefits including reducing (unnecessary) admissions, reducing workload, increased capacity, allowing more focussed treatment and improvement to maternal and foetal safety and outcomes 	

Positive impact on border initiatives, such as:

- National Maternity Review
- 5-Year Forward View for Maternity Care (Feb '16)
- "Better Births": Improving Outcome of Maternity Services in England
- Care and Quality: Capacity in Maternity
- Perinatal Mental Health
- Local Strategic Clinical Network Capacity and Capability Plan

Implementation and adoption

For at least the first 12 months following implementation, the numbers of PE tests requested and the impact on the service (e.g. reduction in admissions, emergency interventions, etc) will be tracked on a quarterly basis to quantify the true impact of the new PE test and pathway on both the Maternity Service and Labs. As with all change, it is expected that there will be an adoption curve until full compliance is reached and the full benefit is realised.

Why is this proposal important to the Trust?

Implementation of PE testing would reduce inpatient admissions whilst improving diagnostic safety. The ability to identify those women not at risk of preeclampsia (the majority) and allow them to safely go home would alleviate worry and anxiety for the woman, allow more focussed care on the at-risk group, reduce unplanned and emergency interventions and prevent unnecessary admission. The availability of these diagnostic tests represents a step change in the management of PE, which is corroborated by NICE. Prior to these tests, the safest option would have been admission and assessment to determine the likelihood of PE. We believe we can now rule out disease with a high Negative Predictive Value.

Evidence of buy-in from stakeholders

Assessment of Estimated Financial and Commissioning Implications

Timescales

Sign off and approval

Quotes

"Eleven NHS England maternity hospitals have evaluated the Quidel Triage PIGF test in a stepped-implementation study where hospitals gradually phased-in PIGF-guided clinical management of suspected preterm pre-eclampsia. When PIGF measurements were revealed to clinicians and midwives, they helped them to identify or exclude pre-eclampsia sooner than they could when PIGF measurements were concealed. Used as part of a clinical management algorithm, PIGF helped clinicians and midwives make more appropriate clinical decisions (i.e., when to schedule the next out-patient clinic appointment, whether to order a specialist ultrasound scan, whether to consider hospital admission, etc.). PIGF-guided clinical management enabled earlier recognition of pre-eclampsia and more appropriate targeting of available interventions, with concomitant improvement in clinical outcomes."

Dr Andrew Shennan OBE MBBS MD FRCOG, Professor of Obstetrics: Clinical Director South London CRN, Department of Women and Children's Health, School of Life Course Sciences, FoLSM, King's College London

"The beauty of these tests is that they are not reliant on analysers that are only available [in Oxford]. The instruments are available at many hospital sites, meaning that the benefits [we have] demonstrated can be expanded across the UK relatively rapidly and easily, and pregnant women everywhere should be able to benefit."

Tim James, OUH Head Biomedical Scientist in Clinical Biochemistry

Bringing pre-eclampsia testing to our unit and enhancing patient pathways was an exciting opportunity. It was a privilege to work with the partnership to successfully introduce this new test at Stoke Mandeville hospital

Dr Maria Zammit-Mangion, Consultant Obstetrician and Gynecologist, Buckinghamshire Healthcare NHS Trust

I was so happy not to be admitted to hospital; knowing I could go home and that I was safe was brilliant

Oxford mother

Having a test that effectively triages patients into high risk and low risk groups means that we can focus our care

Hospital midwife

"Pre-eclampsia is a major cause of maternal and foetal morbidity worldwide and places significant economic and capacity burdens on maternity systems. Through standardisation of sFlt-1/PIGF testing on the ELECSYS platform we will be able to make significant improvements to patient safety and the level of service offered to women"

Dr Manu Vatish, Senior Clinical Fellow in Obstetrics, Oxford John Radcliffe Hospital

Implementation Checklist

Element	Checklist	Organisation
	Spread Status	Knowledge/Interest/ Consideration/implementing /Adopted
Organisation commitment	<p>Does the organisation understand the innovation and the associated complexity?</p> <p>Has clinical review of the innovation been undertaken, and has there been approval for use?</p> <p>Does the organisation understand what is required to implement the innovation (time and cost)? And the desired outcomes?</p> <p>Do other Departments that are key to the implementation understand and support the innovation – e.g. pathology, informatics?</p> <p>Are the reporting arrangements clear – both person accountable and flow of progress reports?</p>	Confirm and describe how the organisation/ system have planned for and will meet these requirements.
System commitment	<p>Is there appropriate commissioner support for implementing the innovation?</p> <p>Which Networks will be taking an interest?</p> <p>How will progress be reported to them?</p> <p>How will the adopter link with other sites that have or plan to implement the innovation?</p>	Confirm and describe how the organisation/ system have planned for and will meet these requirements.
Implementation Team	<p>Is there an executive or senior management sponsor?</p> <p>Is there a clinical lead?</p> <p>Is there a project/ operational manager?</p> <p>Do the clinical lead and project manager have the required capacity and capability?</p>	Confirm and describe how the organisation/ system have planned for and will meet these requirements.

Implementation Checklist

Element	Checklist	Organisation
	Spread Status	Knowledge/Interest/ Consideration/implementing /Adopted
Supporting implementation	<p>What support is available to the implementers?</p> <p>How long is this support available for? Will that be long enough to sustain the implementation?</p>	Confirm and describe how the organisation/ system have planned for and will meet these requirements.
Project Plan	<p>Is there a clear project plan that describes how the adoption will be implemented and timescales?</p> <p>Is it clear when implementation will be complete and effort moves to sustaining it?</p> <p>Are the implementation team and the support available to them going to be in place for the duration of the implementation?</p>	Confirm and describe how the organisation/ system have planned for and will meet these requirements.
Sustaining	<p>How will the people delivering the innovation continue to network with other adopters?</p> <p>Has the adopting team considered how to make this innovation “the way we work around here” / business as usual?</p> <p>How will they receive and share information on its impact?</p>	Confirm and describe how the organisation/ system have planned for and will meet these requirements.
Evaluation	<p>What are the intended outcomes/ benefits of the innovation and how will they be measured?</p> <p>How will these be measured and reported during implementation?</p> <p>How will they be measured and reported once implementation is complete – part of business as usual?</p> <p>Who will undertake the post-implementation evaluation and where will it be reported?</p>	Confirm and describe how the organisation/ system have planned for and will meet these requirements.

Notes

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