

Project scope: PLGF-based testing to help diagnose suspected preterm pre-eclampsia

23 September 2022

Research question

SHTG have been asked to adapt the diagnostics guidance recently produced by NICE on placental growth factor (PLGF)-based testing to help diagnose suspected preterm pre-eclampsia ([1 Recommendations | PLGF-based testing to help diagnose suspected preterm pre-eclampsia | Guidance | NICE](#)). The NICE guidance makes the following recommendations:

1.1 The following placental growth factor (PLGF)-based tests, used with standard clinical assessment, are recommended to help decide on care (to help rule in or rule out pre-eclampsia) for people with suspected preterm (between 20 weeks and 36 weeks and 6 days of pregnancy) pre-eclampsia:

- DELFIA Xpress PLGF 1-2-3
- DELFIA Xpress sFlt-1/PLGF 1-2-3 ratio
- Elecsys immunoassay sFlt-1/PLGF ratio
- Triage PLGF Test

Not all manufacturers indicate their tests for use across the full range of 20 weeks to 36 weeks and 6 days of pregnancy. The tests should be used according to their indications for use (see section 2).

1.2 PLGF-based testing may particularly benefit groups at higher risk of severe adverse pregnancy outcomes, such as people from African, Caribbean and Asian family backgrounds.

1.3 Further research is recommended into how well the tests work when people are pregnant with more than 1 baby.

1.4 Do not use PLGF-based tests to make decisions about whether to offer a planned early birth to people with preterm pre-eclampsia. The NICE guideline on hypertension in pregnancy has recommendations on timing of birth.

1.5 Use a PLGF-based test once per episode of suspected preterm pre-eclampsia. Further research is recommended on repeat testing.

1.6 BRAHMS sFlt-1 Kryptor/BRAHMS PLGF plus Kryptor PE ratio is not recommended for routine use in the NHS. Further research is needed to show the accuracy of this test when using specified thresholds.

Inclusion criteria

The NICE guidance was published in July 2022, and so the evidence base used to inform their recommendations will be used. The literature searches that NICE ran will be updated, using the same inclusion and exclusion criteria.

Planned activities

SHTG has agreed the following activities to support the development of an SHTG Adaptation of the NICE guidance on PLGF-based testing to help diagnose suspected preterm pre-eclampsia:

1. The EUnetHTA Adaptation Toolkit will be used to assess the reliability, relevance and transferability of the NICE guidance to the Scottish context. This will include an assessment of the NICE evidence review. Original studies will only be obtained and reviewed if there is any doubt about the way in which they are reported in the NICE evidence review.
2. A draft adaptation document will be prepared, using the SHTG Adaptation template. This will include a description of the technology; a draft recommendation for NHSScotland (which may differ from NICE's recommendation); and a section on considerations for NHSScotland.
3. A stakeholder analysis will be conducted to ensure that all relevant stakeholders (including patient groups) are invited to contribute to the work in the appropriate manner. Topic referrers will be asked to input to the stakeholder analysis.
3. The draft adaptation document will be sent out to topic experts for comment. Experts will be asked to respond to survey questions relating to the draft adaptation.
4. The draft adaptation document will be amended based on experts' comments, and (if required) a second draft will be sent to the topic experts for comment.
5. Changes will be made to the draft adaptation document based on the comments received. If required, a third draft will be sent out to the topic experts for comment.
6. After the survey exercise, a final draft will be prepared and presented to the SHTG Council for their comments and approval.

End products

At the end of the project, SHTG will publish:

- SHTG Recommendations for Scotland, based on the NICE Diagnostics Guidance on PLGF-based testing to help diagnose suspected preterm pre-eclampsia.

Timescales (approximate)

The work will be considered by the SHTG Council during their meeting in February 2023, and published on the SHTG website in March 2023.