Project scope: Clopidogrel genotype testing after ischaemic stroke or transient ischaemic attack (TIA)

October 2023

Research question

We have been asked to adapt the NICE diagnostics guidance on clopidogrel genotype testing after ischaemic stroke or TIA (https://www.nice.org.uk/guidance/indevelopment/gid-dg10054). The draft guidance makes the following recommendations:

> **1.1** Offer laboratory based clopidogrel genotype testing, or the Genomadix Cube point of care test if laboratory testing is not possible, to people who have had an ischaemic stroke or transient ischaemic attack if treatment with clopidogrel is being considered.
>
> **1.2** Healthcare professionals should take into account that the prevalence of different CYP2C19 genotypes may vary between ethnic groups.
>
> **1.3** There is not enough evidence to recommend the Genedrive CYP2C19 ID Kit. It should only be used in the context of research.
>
> **1.4** Further research is recommended on the Genedrive CYP2C19 ID Kit to determine its accuracy and failure rate.

Inclusion criteria

The NICE guidance is due to be published in December 2023. The evidence base used to inform the NICE draft will be used to inform recommendations for NHSScotland.

Planned activities

SHTG has agreed on the following activities to support the development of an SHTG Adaptation of the NICE guidance on clopidogrel genotype testing after ischaemic stroke or TIA:

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); an adaptation of the NICE economic model 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.
4. 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. The draft adaptation document will be amended based on experts' comments, and (if required) a second and third draft will be sent to the topic experts for comment.
5. After the survey exercise, a final draft will be prepared and presented to the SHTG Council for their comments and approval.
6. We will conduct a budget impact assessment on the implementation of clopidogrel genotype testing in NHSScotland using data from Scotland provided by Public Health Scotland where appropriate.

Public Health Scotland (PHS) has agreed on the following activities to support ANIA decision making on clopidogrel genotype testing after ischaemic stroke or TIA:

7. PHS will conduct an outcome and service impact assessment on the implementation of clopidogrel genotype testing in NHSScotland.

End products

At the end of the project, SHTG will publish:

- SHTG Recommendations for NHSScotland based on the NICE diagnostic guidance on clopidogrel genotype testing after ischaemic stroke or TIA.
- A plain language summary of the SHTG Recommendations.
- A budget impact assessment.

At the end of the project, PHS will publish:

- An outcome and service impact assessment.

Timescales (approximate)

The SHTG Recommendations and budget impact assessment will be considered by the SHTG Council during their meeting in February 2024 and published on the SHTG website in March 2024.

The PHS outcome and service impact assessment will be available in February 2024.