NICE National Institute for Health and Care Excellence

Resource impact summary report

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NICE has recommended CYP2C19 genotype testing to assess if clopidogrel is a suitable antiplatelet for people who have recently had an ischaemic stroke or transient ischaemic attack (TIA). CYP2C19 genotype testing is only recommended if:

- quality assurance processes are in place for point-of-care tests.
- shared decision making for doing the test is established (see the NICE webpage on shared decision making).

The guidance states that the preferred order for the method of testing should be:

- laboratory-based testing, and then
- Genedrive CYP2C19 ID Kit point-of-care test (when laboratory testing is not available), and then
- Genomadix Cube point-of-care test (when neither laboratory-based testing nor the Genedrive CYP2C19 ID Kit point-of-care test are available).

Testing and changing treatment for those found to have loss-of-function (LOF) alleles delivers better outcomes, such as a reduction in the number of strokes over both short and long term. Benefits associated with a reduction in the number of strokes would include fewer hospital admissions, bed day savings, reduction in allied health professional support and social care savings.

Tables 1 to 4 show the estimated number of strokes and bleeding events per 10,000 people who are found to have LOF alleles. These figures have been provided by the external assessment group (EAG) that supported the guidance.

Non-minor stroke population

Table 1 Estimated number of events in 90 days per 10,000 people (per treatment)

Treatment (test result)	Minor stroke (n)	Moderate stroke (n)	Major stroke (n)	Major bleeds (n)	Total (n)
Clopidogrel (No test with LOF alleles present)	131	147	30	32	340
Dipyridamole and aspirin (Positive laboratory test – LOF alleles present)	94	105	21	36	256
Aspirin (Positive laboratory test – LOF alleles present)	125	140	2	21	288
Ticagrelor (Positive laboratory test – LOF alleles present)	105	117	24	26	272

Table abbreviations: LOF, loss of function.

Table 2 Estimated number of events in 5 years per 10,000 people (per treatment)

Treatment (test result)	Minor stroke (n)	Moderate stroke (n)	Major stroke (n)	Major bleeds (n)	Total (n)
Clopidogrel (No test with LOF alleles present)	1,207	1,461	330	559	3,557
Dipyridamole and aspirin (Positive laboratory test – LOF alleles present)	928	1,111	245	630	2,914
Aspirin (Positive laboratory test – LOF alleles present)	1,173	1,408	290	379	3,250
Ticagrelor (Positive laboratory test – LOF alleles present)	1,019	1,218	271	469	2,977

Table abbreviations: LOF, loss of function.

Transient ischaemic attack or minor stroke population

Table 3 Estimated number of events in 90 days per 10,000 people (per treatment)

Treatment (test result)	Minor stroke (n)	Moderate stroke (n)	Major stroke (n)	Major bleeds (n)	Total (n)
Clopidogrel (No test with LOF alleles present)	103	115	24	27	269
Dipyridamole and aspirin (Positive laboratory test – LOF alleles present)	74	82	17	31	204
Aspirin (Positive laboratory test – LOF alleles present)	98	109	2	18	228
Ticagrelor (Positive laboratory test – LOF alleles present)	82	92	19	23	216

Table abbreviations: LOF, loss of function.

Table 4 Estimated number of events in 5 years per 10,000 people (per treatment)

Treatment (test result)	Minor stroke (n)	Moderate stroke (n)	Major stroke (n)	Major bleeds (n)	Total (n)
Clopidogrel (No test with LOF alleles present)	419	486	104	593	1,601
Dipyridamole and aspirin (Positive laboratory test – LOF alleles present)	312	361	77	658	1,408
Aspirin (Positive laboratory test – LOF alleles present)	405	466	79	401	1,350

Treatment (test result)	Minor stroke (n)	Moderate stroke (n)	Major stroke (n)	Major bleeds (n)	Total (n)
Ticagrelor (Positive laboratory test – LOF alleles present)	346	399	85	492	1,322

Table abbreviations: LOF, loss of function.

Areas that will or may need additional resources and result in additional costs include:

- resources needed to expand capacity within both hospitals and NHS Genomic Laboratory Hubs so that they can do the tests and convey the results
- costs associated with laboratory testing, such as device and reagent costs
- costs associated with point-of-care tests, such as the cost of the device(s), control kits, warranties and any costs associated with managing the supply contracts
- time needed for training NHS staff
- any costs associated with recording the results on electronic patient record systems
- increased medication costs in relation to those who are found to have LOF alleles.

Implementing laboratory-based CYP2C19 genotype testing for everyone who has a stroke or TIA would result in a large population being tested, which may need testing capacity to be scaled up over time. When implementing testing, commissioners may wish to consider:

- a phased rollout with testing initially offered to people with a higher risk of stroke recurrence who could benefit most from it, such as people who have had a non-minor stroke.
- point-of-care testing as an alternative if laboratory-based testing is not feasible at this scale, or while capacity for laboratory-based testing is increased.

Because of the variation in capacity to deliver laboratory-based testing for the eligible population, the size and implications of the resource impact will need to be determined at a local level. So, a local resource impact template has been produced to help organisations to estimate the resource impact. Organisations can use this template to understand the resources involved in expanding capacity to deliver laboratory-based and point-of-care testing.

The template has sheets for users to note the resources and costs associated with testing. This is a summary of each worksheet:

Assumptions input – On this worksheet, users can show how many people are tested for LOF alleles in current practice and determine the populations they intend to test in future practice, outlining what portion of tests will be done in a laboratory and what portions will use the recommended point-of-care tests.

In the relevant cells in rows 51 to 53, users will need to input the rates of testing and in the corresponding cells in rows 67 to 68 the proportion of each type of test used. In the relevant cells in rows 89 to 91, users should note the spread of alternative treatments for those found to have LOF alleles. An indication of the number of strokes and bleeding events per 10,000 people with LOF alleles per treatment is summarised in the tables shown in rows 99 to 135.

At the bottom of the worksheet users can model the capacity implications of testing. Costs related to salaries are derived from the pay scales worksheet and can be amended here at a local level. The pay scales worksheet uses agenda for change pay scales and includes employer on-costs. Users can change the time spent on each activity and the staff grade to reflect their local circumstances.

Unit costs – This worksheet enables users to input the cost of the drug treatment options and the costs of doing the tests (excluding human resource costs, which are captured in the assumptions worksheet).

Summary – This worksheet summarises the numbers tested, together with the cost of testing and cost of antiplatelet treatments. In cell B26 users can choose whether to model the capacity implications for either laboratories or hospitals.

Financial impact (cash) –This worksheet outlines the costs of the testing and the anticipated increases to drug costs in comparison to treatment with clopidogrel.

Capacity impact - labs – This worksheet highlights the resources needed in laboratories for the testing levels outlined in the assumptions input worksheet. An indication as to how many whole-time equivalent positions this equates to is also given.

Capacity impact - hospitals – This worksheet highlights the resources needed in hospitals for the testing levels outlined in the assumptions input worksheet. An indication as to how

many whole-time equivalent positions this equates to is also given.

Services for people who have had a stroke are commissioned by integrated care boards, except for specialist neurosurgical interventions such as thrombectomy that are commissioned by NHS England.

NHS hospital trusts, including adult neurosciences or neurology centres and ambulance services, provide stroke care. There are 7 NHS Genomic Laboratory Hubs in England that can perform genomic testing.

About this resource impact summary report

This resource impact summary report accompanies NICE's diagnostics guidance on CYP2C19 genotype testing to guide clopidogrel use after ischaemic stroke or transient ischaemic attack, and should be read with it. See the terms and conditions on the NICE website.