



## EQIA Details

<b>Name:</b> (policy/ procedure/ practice/ function)	<b>Stroke Clopidogrel_Neonatal Gentamicin Genotype Testing</b>
<b>Department:</b>	<b>CfSD – Innovation Team - ANIA</b>
<b>Lead Contact:</b>	<b>Jennifer Wilson /Suzanne Graham</b>
<b>EQIA Assessor:</b>	<b>Catriona Macdonald/ Emma MacLaren</b>
<b>Date:</b>	<b>01-09-23 (updated 21-05-24)</b>

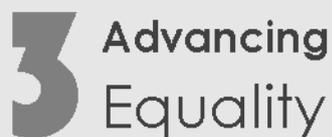
Use this section to provide details about the status (**new or existing**) of the policy/practice/procedure/function and provide an outline of the proposal including **aims, objectives** and **outcomes**.

Please note: All tables within this report are expandable.

Status	New <input checked="" type="checkbox"/> Existing <input type="checkbox"/>
<b>Aims objectives &amp; outcomes</b>	<p><b>OBJECTIVE</b> This project proposes the national deployment of two new genetic tests across Scotland, adopting a precision medicine approach, improving patient outcomes (fewer strokes and preventing infant deafness).</p> <p><b>1a. Lab based CYP2C19 genotype testing -</b> Clopidogrel is an anti-platelet medication that is widely prescribed throughout the NHS after a stroke, transient ischaemic attack (TIA) and is critical for preventing further similar events. In the UK, an estimated 28.7% of people prescribed clopidogrel are resistant to this drug [1]. This means they cannot metabolise (process) clopidogrel, so their stroke risk is not reduced. Clopidogrel resistance can be caused by mutations in the CYP2C19 gene. Relevant CYP2C19 gene variants can be identified using genotype testing, allowing clinicians to prescribe a more effective antiplatelet medication. These patients can be identified easily by a simple genetic blood test, which identifies the presence of variations with the CYP2C19 gene. If the test shows that Clopidogrel will not be effective, doctors or pharmacists can then choose alternative anti-platelet treatments. In Scotland, 9,373 people had a confirmed ischaemic stroke in 2023, which accounts for 85% of all strokes [1]. An estimated 7,030 (75%) of these people had a non-cardioembolic ischaemic stroke. Approximately 3,763 people had a TIA in Scotland in 2023 (69 TIAs per 100,000 population). An estimated 12.1% of people who have had a first non-cardioembolic stroke or TIA have a recurrent stroke within 5 years. People who have a non-cardioembolic ischaemic stroke or TIA are often prescribed antiplatelet medications, such as clopidogrel, to reduce their risk of another stroke [1]. In Scotland, NHS Tayside ran a clinical study between 2022 and 2023 to test the use of this genomic test in an operational setting. 723 patients were tested and 169 of these patients had their prescription switched from clopidogrel to an alternative anti-platelet medication. Through analysis, NHS Tayside estimated that during the trial, 17 fewer strokes occurred due to patients being prescribed the correct anti-platelet medication [2]. Following the successful trial, NHS Tayside approved the CYP2C19 genotype test as a permanent service. Patients in other Health Boards do not currently have access to this genotype test.</p> <p><b>1b. CYP2C19 POCT (Test of Change) -</b> The draft NICE guidelines, currently out for consultation, recommend lab-based genetic testing of CYP2C19 as the main means of identifying the gene variant. The guidelines state use of the Genedrive POCT kit if lab-based testing is not available or whilst the lab-based testing is being scaled up [3]. The turnaround time for</p>

Lab-based testing is currently 7 days whereas the POCT can provide results within an hour. POCT could increase equity across Scotland especially across the Islands and rural areas where sample transport to genetic labs would take longer.

2. M.1555A>G POCT - Gentamicin is one of five aminoglycoside antibiotics which is a low cost, widely prescribed drug used in neonatal care nationally. Neonates that have the MT-RNR1 m.1555A>G gene variant have an increased risk of developing permanent hearing loss if they are given the antibiotic gentamicin. Around 1,249 babies are born in England and Wales with the variant each year [4]. It is estimated that 1 in 500 have this gene variant and when considering the birth rate for Scotland, this equates to approximately 90 babies per year. Currently babies treated with gentamicin who go deaf are only discovered to have the genetic variant upon further investigation into the reason for their deafness. The referral relates to the Pharmacogenetics to Avoid Loss of Hearing (PALOH) trial, which demonstrated that a new point of care genetic test could quickly identify new-born babies that were vulnerable to deafness if treated with gentamicin [5]. Following the publication of the PALOH study, the genetic test has been conditionally recommended by NICE for use within the NHS [6]. Hearing loss significantly impacts a baby's speech, language, and social development, especially the severe type associated with gentamicin. Whilst a deaf baby can undergo an operation later in infancy to receive cochlear implantation, this does not restore normal hearing but rather enables the child to hear electronically generated sounds. Children with cochlear implants will require both technological supports, such as classroom induction loops, and specialist therapeutic and educational support throughout their early years and school career. Parents of deaf children will also be able to claim for the Child Disability Payment in Scotland. Current testing for M.1555A>G has a four-six-week turnaround time, whereas POCT can identify neonates with this specific gene variant and allow clinicians to administer an alternative, equally effective antibiotic within one hour, which is in line with guideline recommendations. Any delay to antibiotic administration risks life-threatening infection. Overall, this POCT could potentially stop the permanent hearing loss caused by aminoglycoside antibiotics in neonates, improving patient quality of life and reducing the cost burden on NHS services.



NHS Golden Jubilee has a legal requirement under the Public Sector Equality Duty to have due regard to the need to:

- › Eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the Act.
- › Advance equality of opportunity between people who share a protected characteristic and those who do not.

- › Foster good relations between people who share a protected characteristic and those who do not.

Provide details of how the work will impact **positively**, **negatively** or **neutrally** on people who share the characteristics below.

It will be helpful to consider any access issues, health inequalities or experiences of discrimination that might impact these groups within your area of work. It will also be helpful to think about human rights and whether these will be impacted for any group. Our rights are described in the [Human Rights Act](#). Some groups are also protected by specific conventions, which are highlighted for your information in the relevant sections below.

There is no word count – you should include the information you think is required. Please ensure the information you use is evidence based (e.g. articles, public involvement, previous work). There is space at section 8 for you to record the evidence sources you use in your assessment.

 <b>Age</b>	<p>Think about older people as well as children and young people, and their respective carers.</p> <p>If children are specifically affected, use a Children’s Rights and Wellbeing Impact Assessment to provide more information. Consider our child protection policy.</p> <p><a href="#">Convention on the Rights of the Child</a></p>
Positive impact	<p>CYP2C19 genotype testing - With the increased risk of a TIA and stroke as you age the introduction of this blood test could prevent patients having further episodes.</p> <p>M.1555A&gt;G POCT – The introduction of this test for neonates could prevent the risk of permanent hearing loss caused by gentamicin ototoxicity. The test result will remain with the patient throughout their life.</p>
Negative impact	<p>M.1555A&gt;G POCT – As per the NICE guidelines only neonates will be considered for testing within this project, meaning patients older than 28 days old may be prescribed gentamicin without access to this test and hence the risk factor remains in this group.</p>

Neutral impact	CYP2C19 genotype testing - Only patients deemed clinically appropriate for Clopidogrel will be tested. The likelihood of anyone under 18 being tested is very low as clopidogrel should only be prescribed to them under specialist advice.
 <b>Care Experience</b>	Think about children and young people up to the age of 26 who have experience of being in care. This can include foster care/supported care, kinship care, residential care, or being looked after at home with the support of a supervision order.  NHS Golden Jubilee is named as a corporate parent under the <a href="#">Children and Young People (Scotland) Act 2014</a> . You can find information and working examples of what this means for us in our <a href="#">Corporate Parenting Plan</a> .
Positive impact	> N/A
Negative impact	> N/A
Neutral impact	> The introduction of both tests should have a neutral impact on this protected characteristic.
 <b>Disability</b>	Think about people with sensory impairments, communication difficulties, learning disabilities, physical impairments, energy impairments, autism spectrum disorders, mental health conditions and Deaf users of British Sign Language. You might also consider unpaid carers here.  <a href="#">Convention on the Rights of Person with Disabilities</a>
Positive impact	CYP2C19 genotype testing - Certain disabilities may mean a patient is of higher risk of TIA / stroke so the introduction of this test will be a positive impact. M.1555A>G POCT- Introduction of this test can prevent neonates going deaf, therefore improving their quality of live, and reducing the chance of the child growing up with a disability.
Negative	N/A
Neutral impact	N/A

 <b>Trans Status</b>	<p>This is about trans / transgender people - anyone whose gender does not match the sex they were assigned at birth.</p> <p><a href="#">Understanding the Transgender Community – Human Rights Campaign</a></p>
Positive impact	CYP2C19 genotype testing - Depending upon any increased risk due to hormonal medication or medical procedures / surgery then the introduction of this test has a positive impact.
Negative impact	N/A
Neutral impact	M.1555A>G will have neutral impact on this protective characteristic.
 <b>Marriage &amp; Civil Partnership</b>	<p>Are there any implications for people who are married or in a civil partnership?</p> <p><a href="#">Marriage and civil partnership discrimination – Citizen's Advice Bureau</a></p>
Positive impact	N/A
Negative impact	N/A
Neutral impact	The introduction of both tests should have a neutral impact on this protected characteristic.
 <b>Pregnancy &amp; Maternity</b>	<p>Think about people who are pregnant, breast-feeding or who recently gave birth.</p> <p><a href="#">Convention on the Elimination of All Forms of Discrimination against Women</a></p>
Positive impact	<p>CYP2C19 Genotype Testing - Depending upon any increased risk due to medication, any pregnancy complications or medical procedures then the introduction of this test has a positive impact.</p> <p>M.1555A&gt;G POCT –</p> <p>If neonate is identified as carrying this gene variant, they will be prescribed an alternative antibiotic eliminating the risk of permanent hearing loss from ototoxicity. Avoiding a neonate experiencing permanent hearing loss will positively impact upon the mother as well as the child.</p>
Negative impact	N/A
Neutral impact	CYP2C19 Genotype Testing - Only patients deemed clinically appropriate for clopidogrel will be tested. Clopidogrel is not recommended during pregnancy or

	whilst breastfeeding, therefore the number of patients tested will be low.
 <b>Race</b>	<p>Think about people with non-white majority ethnicities. This includes gypsy/travellers.</p> <p><a href="#">Convention on the Elimination of all forms of Racial Discrimination</a></p>
Positive impact	<p>CYP2C19 Genotype testing - As some ethnic groups have a higher prevalence of CYP2C19 LOF alleles, (60% in Asian heritage compared to 30% in European heritage) then the introduction of this blood test will be beneficial.</p> <p>M.1555A&gt;G POCT - Further research is required to understand the prevalence of this gene variant in different ethnic groups.</p>
Negative impact	<p>CYP2C19 Genotype Testing - The lab-based test only detects the most common loss-of-function alleles *2 and *3. It has been estimated that the combined prevalence of *4, *8 and *35 alleles in the UK is around 0.6%. It has been noted that the *35 allele has a prevalence of up to 3% in people with sub-Saharan African family background, and that the *4 allele is more common in the Ashkenazi Jewish population. In summary, as the lab-based CYP2C19 genotype test only test for loss of function alleles *2 and *3 the test would likely disproportionately fail to identify people with loss-of-function CYP2C19 alleles in certain ethnic groups.</p> <p>M.1555A&gt;G POCT – N/A</p>
Neutral impact	N/A
 <b>Religion or Belief</b>	<p>Think about people who follow particular religions. For example: Judaism, Islam, Sikhism, Christianity etc. Are there particular beliefs or practices that might be impacted?</p> <p><a href="#">International standards on freedom of religion or belief</a></p>
Positive impact	N/A
Negative impact	N/A

Neutral impact	The introduction of both tests should have a neutral impact on this protected characteristic.
 <b>Sex</b>	Think about any differences for women compared to men, or vice versa. <a href="#">Convention on the Elimination of all forms of Discrimination Against Women</a>
Positive impact	N/A
Negative impact	N/A
Neutral impact	The introduction of this test should have a neutral impact on this protected characteristic.
 <b>Sexual Orientation</b>	Think about people who are lesbian, gay or bi or who have another minority sexual orientation (e.g. are not heterosexual / straight). <a href="#">Combatting discrimination based on sexual orientation</a>
Positive impact	N/A
Negative impact	N/A
Neutral impact	The introduction of both tests should have a neutral impact on this protected characteristic.
 <b>Socio-economic</b>	Think about people living on low incomes and / or in deprived areas. If this is a strategic-level decision and the Fairer Scotland duty applies, you will need to give this characteristic detailed consideration. Otherwise, consider this as a cross-cutting issue (people who share a protected characteristic are more likely to experience poverty). <a href="#">The Fairer Scotland Duty Interim Guidance for Public Bodies</a>
Positive impact	CYP2C19 Genotype Testing - The rate in the most deprived quintile increased by 39% compared to 21% in the least deprived quintile. Therefore, the introduction of this test will have a positive impact upon this protected characteristic.
Negative impact	N/A
Neutral impact	M.1555A>G POCT - only neonates admitted to neonatal units will have access to the genetic test

# 4 Overcoming Negative Impacts

Where the policy/practice/procedure/function was identified to adversely affect (discriminate against) people who share a protected characteristic; provide details of how this impact will be eliminated, minimised or managed.

Protected Characteristic	Actions	Person Responsible
<b>All Characteristics</b>	Click or tap here to enter text.	Click or tap here to enter text.
 Age	<b>CYP2C19 Genotype testing - Individualised care plan if below 18 as alternative medication is required</b>	<b>Stroke Consultant</b>
 Care Experience	N/A	N/A
 Disability	N/A	N/A
 Trans Status	N/A	N/A
 Marriage/Civil Partnership	N/A	N/A
 Pregnancy & Maternity	<b>CYP2C19 Genotype Testing - Clopidogrel not recommended during pregnancy / breast-feeding so alternative maybe required during this time.</b>	<b>Stroke Consultant and Maternity Team</b>
 Race	N/A	N/A
 Religion or Belief	N/A	N/A
 Sex	N/A	N/A
 Sexual Orientation	N/A	N/A

£	Socio-economic	N/A	N/A
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## 5 Impact Rating

Provide an impact rating based on the degree to which the policy/practice/procedure/function will impact people who share a protected characteristic.

### Impact Rating Key



**Low**

There is **little or no evidence** that some people are (or could be) differently affected by the policy/practice/procedure/function.



**Medium**

There is **some evidence** that people are (or could be) differently affected by the policy/practice/procedure/function.



**High**

There is **substantial evidence** that people are (or could be) differently affected by the policy/procedure/decision

Protected Characteristic		Low	Medium	High
	Age	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Care Experience	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Disability	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Trans Status	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Marriage/Civil Partnership	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Pregnancy & Maternity	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Race	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Religion or Belief	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Sex	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Sexual Orientation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Socio-economic	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Provide details of stakeholder collaboration and consultation.

Refer to **Appendix A** for details of local and national charities and user groups which represent the Protected Characteristics defined by the Equality Act 2010.

Name and Job title	Department or Organisation	Contact details
Tosh Lynch	Spiritual Care Lead	Tosh.lynch@gjnh.scot.nhs.uk

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## 7 Monitor & Review

Regular reviews ensure that the policy, procedure or practice is kept up to date, and meets the requirements of current equality legislation.

Scheduled Review	Assigned contact	Review Date
	Catriona Macdonald	10-04-24
Catriona Macdonald/Emma Maclaren	26-08-24	

Where a negative impact has been identified and remedial actions are being implemented, the policy owner should define a timescale for review.

Identified Issue	Assigned contact	Review Date
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

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## 8 Evidence & Research

Please detail all evidence and research utilised in order to support the rationale for this EQIA. (Include attachments where available).



[Equalities Evidence Finder](#)

### Evidence & Research



Click or tap here to enter text.



## 9 EQIA Sign-Off

### EQIA's with low impact ratings

If your EQIA demonstrates low impact ratings for each Protected Characteristic, then you are all set to go!

Please ensure that you email a copy of your EQIA to [equalities@gjnh.scot.nhs.uk](mailto:equalities@gjnh.scot.nhs.uk) to allow us to maintain a central database of assessments for auditing purposes.



[equalities@gjnh.scot.nhs.uk](mailto:equalities@gjnh.scot.nhs.uk)



## EQIA's with medium or high impact ratings

If your EQIA has identified any **medium** or **high impacts** for people who share a Protected Characteristic, you will need to share your assessment with the Service Design and Equalities Lead who will review and advise next steps.



**Rob White: Service Design and Equalities Lead**



[robert.white@gjnh.scot.nhs.uk](mailto:robert.white@gjnh.scot.nhs.uk)



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## Organisational governance process

Next, you need to share the EQIA with the people you're working with on your project, policy, process or practice. Not least because you should be proud of your work, but also because you should communicate the results of your assessment to project boards, organisational leaders, key stakeholders and others in a timely way, so that they can make informed decisions about the change you're making.

**EQIA Assessor:**

Click or tap here to enter text.

**Diversity and Inclusion Group Representative:**

Click or tap here to enter text.

**Sign-Off Date:**

Click or tap here to enter text.  
<mailto:dawn.mcneil@stath.ac.uk>

	Age	<ul style="list-style-type: none"> <li>▪ Age UK</li> </ul>	<a href="http://www.ageuk.org.uk">www.ageuk.org.uk</a>
	Care Experience	<ul style="list-style-type: none"> <li>▪ Become</li> </ul>	<a href="https://www.becomecharity.org.uk/">https://www.becomecharity.org.uk/</a>
		<ul style="list-style-type: none"> <li>▪ CELCIS</li> </ul>	<a href="http://www.celcis.org">www.celcis.org</a>
		<ul style="list-style-type: none"> <li>▪ Who Cares? Scotland</li> </ul>	<a href="http://www.whocarescotland.org">www.whocarescotland.org</a>
		<ul style="list-style-type: none"> <li>▪ SCCYP</li> </ul>	<a href="http://www.sccyp.org.uk">www.sccyp.org.uk</a>
	Disability	<ul style="list-style-type: none"> <li>▪ RNIB Scotland</li> </ul>	<a href="http://WWW.RNIB.ORG.UK">WWW.RNIB.ORG.UK</a>
		<ul style="list-style-type: none"> <li>▪ Visibility</li> </ul>	<a href="http://WWW.VISIBILITY.ORG.UK">WWW.VISIBILITY.ORG.UK</a>
		<ul style="list-style-type: none"> <li>▪ Action on Hearing Loss</li> </ul>	<a href="http://www.actiononhearingloss.org.uk">www.actiononhearingloss.org.uk</a>
		<ul style="list-style-type: none"> <li>▪ Dementia UK</li> </ul>	<a href="http://www.dementiauk.org">www.dementiauk.org</a>
		<ul style="list-style-type: none"> <li>▪ Alzheimer's Society</li> </ul>	<a href="http://www.alzheimers.org.uk">www.alzheimers.org.uk</a>
		<ul style="list-style-type: none"> <li>▪ Autism Alliance</li> </ul>	<a href="http://www.autism-alliance.org.uk">www.autism-alliance.org.uk</a>

		<ul style="list-style-type: none"> <li>▪ Scottish Autism <a href="http://www.scottishautism.org">www.scottishautism.org</a></li> </ul>	
		<ul style="list-style-type: none"> <li>▪ Mind <a href="http://www.mind.org.uk">www.mind.org.uk</a></li> </ul>	
		<ul style="list-style-type: none"> <li>▪ Scope <a href="http://www.scope.org.uk">www.scope.org.uk</a></li> </ul>	
	Trans Status	<ul style="list-style-type: none"> <li>▪ <a href="mailto:dawn.mcneil@stat.h.ac.uk">mailto:dawn.mcneil@stat.h.ac.uk</a> Scottish Trans Alliance <a href="http://www.scottishtrans.org">www.scottishtrans.org</a></li> </ul>	
		<ul style="list-style-type: none"> <li>▪ Sparkie <a href="http://www.sparkie.org.uk">www.sparkie.org.uk</a></li> </ul>	
		<ul style="list-style-type: none"> <li>▪ Mermaids UK <a href="http://www.mermaidsuk.org.uk">www.mermaidsuk.org.uk</a></li> </ul>	
	Marriage/ Civil Partnership	<ul style="list-style-type: none"> <li>▪ Equality Network <a href="http://www.equality-network.org">www.equality-network.org</a></li> </ul>	
	Pregnancy & Maternity	<ul style="list-style-type: none"> <li>▪ Maternity Action <a href="http://www.maternityaction.org.uk">www.maternityaction.org.uk</a></li> </ul>	
	Race	<ul style="list-style-type: none"> <li>▪ Race Equality Foundation <a href="http://www.raceequalityfoundation.org.uk">www.raceequalityfoundation.org.uk</a></li> </ul>	
		<ul style="list-style-type: none"> <li>▪ Ethnic Minority Foundation <a href="http://www.emfoundation.org.uk">www.emfoundation.org.uk</a></li> </ul>	
	Religion or Belief	<ul style="list-style-type: none"> <li>▪ Interfaith Scotland <a href="http://www.interfaithscotland.org">www.interfaithscotland.org</a></li> </ul>	
	Sex	<ul style="list-style-type: none"> <li>▪ Equality Now <a href="http://www.equalitynow.org">www.equalitynow.org</a></li> </ul>	

	<ul style="list-style-type: none"> <li>Fawcett Society</li> </ul>	<a href="http://www.fawcettsociety.org.uk">www.fawcettsociety.org.uk</a>
 Sexual Orientation	<ul style="list-style-type: none"> <li>Stonewall Scotland</li> </ul>	<a href="http://www.stonewall.org.uk">www.stonewall.org.uk</a>
	<ul style="list-style-type: none"> <li>West Dunbartonshire LGBT Network</li> </ul>	<a href="http://www.lgbtwestdunbartonshire.com">www.lgbtwestdunbartonshire.com</a>
	<ul style="list-style-type: none"> <li>LGBT Youth Scotland</li> </ul>	<a href="http://www.lgbtyouth.org.uk">www.lgbtyouth.org.uk</a>
 Socio-economic	<ul style="list-style-type: none"> <li>The Poverty Alliance</li> </ul>	<a href="http://www.povertyalliance.org">www.povertyalliance.org</a>
	<ul style="list-style-type: none"> <li>Citizens Advice</li> </ul>	<a href="http://www.citizensadvice.org.uk">www.citizensadvice.org.uk</a>

## References

- [1] SHTG Assessment (cannot link as not a published document until Oct)
- [2] Stroke Clopidogrel Value Assessment
- [3] [CYP2C19 genotype testing to guide clopidogrel use after ischaemic stroke or transient ischaemic attack \(nice.org.uk\)](http://nice.org.uk)
- [4] [Genetic test developed by Manchester researchers to prevent newborn babies going deaf recommended by NICE - Manchester University NHS Foundation Trust \(mft.nhs.uk\)](http://mft.nhs.uk)
- [5] [Pharmacogenetics to Avoid Loss of Hearing \(PALOH\) trial: a protocol for a prospective observational implementation trial | BMJ Open](#)
- [6] [NICE recommends genetic test to prevent newborn babies going deaf | NICE](#)