

# Project scope: genotype testing to detect the m.1555A>G variant in neonates to guide use of aminoglycosides

April 2024

## Research question

1. What is the clinical effectiveness, cost effectiveness and safety of aminoglycoside (gentamicin) genotype testing compared with no testing in neonates?

## Inclusion criteria

The selection of studies for inclusion in the literature review element of the project will be based on the following criteria:

<b>Population</b>	Neonates who need antibiotic treatment and are being considered for aminoglycosides (most commonly gentamicin)
<b>Intervention/exposure</b>	Genotype testing (for the m.1555A>G mutation/variant in the MT-RNR1 gene)
<b>Comparator</b>	No testing
<b>Outcomes</b>	Hearing loss/deafness Mortality Quality of life Cost effectiveness Safety

## Planned activities

SHTG have agreed on the following activities to support an SHTG Assessment on genotype testing to detect the m.1555A>G variant in neonates:

1. A summary of the clinical effectiveness, cost effectiveness and safety evidence.

2. A budget impact assessment on the implementation of genotype testing in neonates in NHSScotland using data from Scotland provided by Public Health Scotland where appropriate.
3. Development of a plain language version of the SHTG Assessment.
4. Engagement with clinical experts through peer review.

## End products

At the end of the project, SHTG will publish:

- An SHTG Assessment including a budget impact assessment for NHSScotland.
- A plain language summary of the SHTG Assessment.

## Timescales (approximate)

The SHTG Assessment will be published on the SHTG website in September 2024.