Scottish Health Technologies Group (SHTG) Technical Assessment Summary: Genetic testing to guide antibiotic use and prevent hearing loss in newborn babies

MT-RNR1

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Referred by: The Accelerated National Innovation Adoption (ANIA) collaborative
Reference: Harbour J, Heggeland M, Bates E, Chappell J, Herbert P, Lakha F, Lee A, Nicol T. (2024). Genotype testing to guide antibiotic use and prevent hearing loss in neonates. Glasgow/Edinburgh; NHS Healthcare Improvement Scotland.
Available at: https://shtg.scot/our-advice/genotype-testing-to-guide-antibiotic-use-and-prevent-hearing-loss-in-babies/

Key findings

- Newborns with the MT-RNR1 gene variant, m.1555A>G, have an increased risk of permanent hearing loss if treated with aminoglycoside antibiotics.
- The Genedrive® MT-RNR1 ID Kit is a point-of-care genetic test providing results in approximately 26 minutes, without delaying antibiotic treatment.
- Implementation in Scottish NICUs could prevent hearing loss in three babies over three years, avoiding approximately £180,000 in cochlear implant costs.

Who is SHTG?

The Scottish Health Technologies Group (SHTG) is a national health technology assessment (HTA) agency that provides impartial, evidence-based advice to NHSScotland on the use of health technologies.
This advice aims to inform effective, safe, and best value use of health technologies, supporting informed decision making that improves healthcare across Scotland.

Purpose of the assessment

This assessment was performed in response to enquiry from the Accelerated National Innovation Adoption (ANIA) collaborative that works within NHSScotland to fast-track the adoption of proven healthcare innovations. Assessment findings will be used to inform an ANIA value case for the potential implementation of neonatal MT-RNR1 genotype testing in Scotland.

What was assessed?

The SHTG reviewed published literature on the clinical effectiveness, safety, cost impact, and patient experience of MT-RNR1 genotype testing to guide antibiotic use in neonates and calculated the effects of introducing this genetic testing in Scotland.

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Why is this important?

- Permanent hearing loss affects children's communication, social and emotional development, and quality of life.
- Approximately 1 in 500 newborns carry the m.1555A>G variant.
- Neonates with suspected infections require antibiotics within one hour, demanding rapid testing solutions.
- Preventing antibiotic induced hearing loss means these children will not experience a lifetime of deafness, and reduces the need for cochlear implants and lifelong audiological care.

MT-RNR1

Clinical evidence

- The Genedrive MT-RNR1 ID Kit demonstrated 100% sensitivity and 99.2% specificity in the PALOH trial.
- Of 424 neonates successfully tested, three were positive for the m.1555A>G variant and avoided hearing loss by receiving alternative antibiotics. Five false positives occurred; no false negatives were reported.
- Failure rates have dropped from 17.1% to 1.8% since the completion of the PALOH trial due to system improvements.
- Results are available within 26 minutes, allowing timely antibiotic administration.
- Successfully integrated into NICU workflows, requiring minimal staff training.

Cost and resource impact

- The NICE cost-effectiveness model and resource impact template were adapted for Scotland.
- The introduction of Genedrive point-of-care testing in Scottish NICUs could prevent three cases of hearing loss caused by aminoglycoside antibiotics over three years.
- The first year sees an increased cost due to initial capital and per-test expenses.
- Long-term savings arise from avoided cochlear implant and audiology costs, with subsequent years yielding net savings.
- By avoiding the need for cochlear implants, the NHS could reduce spending on audiological care by approximately £180,000 over three years.

Considerations and future research

- Although effective, alternative antibiotics have a higher risk of antimicrobial resistance but this is likely a low risk as few babies will have the gene variant.
- Insights from parents, neonatal healthcare professionals, and forum discussions emphasised the importance of clear treatment information and supported the feasibility of integrating the test into neonatal care workflows.
- Additional studies are needed to:
- validate findings in diverse care settings and in a range of geographical areas.
- assess broader societal and quality of life impacts of MT-RNR1 genotype testing.

Conclusions

Babies with the MT-RNR1 gene mutation are at increased risk of hearing loss if given gentamicin to treat infection. Genetic testing can quickly identify this mutation, allowing doctors to prescribe alternative antibiotics without delaying treatment.

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