NICE Early Value Assessment Guideline for Genedrive® MT-RNR1 ID Kit (HTE6)

Who is the National Institute of Clinical Excellence (NICE)?

NICE is a UK organisation with a remit to balance the best care with value for money across the NHS and social care, to deliver for both individuals and society as a whole.

NICE do this by:

- providing rigorous, independent assessment of complex evidence to produce guidance and advice for health and social care practitioners
- developing recommendations that drive innovation into the hands of health and care professionals encouraging the uptake of best practice to improve outcomes for everyone

What is the NICE Early Value Assessment (EVA)?

The NICE Early Value Assessment (EVA) allows rapid assessment of technologies that address national unmet needs to provide a recommendation for early use, enabling the NHS and patients to benefit from the promising technologies sooner.

Key Information

The NICE EVA recommends the use of the Genedrive® MT-RNR1 ID Kit for the prevention of antibiotic-induced hearing loss in newborn babies. The test is a rapid, point of care test that can be used to screen babies for the MT-RNR1 m.1555A>G gene variant, which predisposes carriers to hearing loss when prescribed aminoglycoside antibiotics.

The guidance was developed following a review of evidence by the NICE diagnostics advisory committee. The committee found that the Genedrive® MT-RNR1 ID Kit is a safe and effective test for the prevention of antibiotic-induced hearing loss. The committee also found that the benefits of the test outweigh the risks and costs.

Key recommendations

1. The **Genedrive® MT-RNR1 ID Kit can be used in the NHS, while further evidence is generated**, as an option for detecting the genetic variant m.1555A>G to guide antibiotic (aminoglycoside) use and prevent hearing loss in newborns who are being considered for treatment with aminoglycosides.
2. Healthcare professionals should tell parents about the possible implications of positive test results for their baby and their family at an appropriate time and give support and information.
3. Positive results should be confirmed by laboratory testing.
4. The recommendation is conditional on further evidence being generated.

"Until now there has not been a test quick enough to ensure that newborn babies with a bacterial infection and the m.1555A>G variant gene are treated with an appropriate antibiotic. Having this test available to NHS staff can avoid the risk of hearing loss in babies with the variant who need treatment with antibiotics. Our independent committee has rapidly assessed the evidence for this simple swab test and NICE is conditionally recommending it be used within the NHS while further evidence is generated. "

- Mark Chapman, interim director of Medical Technology at NICE

Reference: NICE. 2023. Genedrive MT-RNR1 ID Kit for detecting a genetic variant to guide antibiotic use and prevent hearing loss in babies: early value assessment https://www.nice.org.uk/guidance/hte6

Summary

Neonatal bacterial infection is a significant cause of death and illness in newborn babies. The NICE guideline on neonatal infection recommends treating suspected early-onset infection in babies with benzylpenicillin and gentamicin. This should be given as soon as possible and always within 1 hour of the decision to treat.

- Gentamicin is the first-choice antibiotic because it is active against a wide range of bacteria and has a low risk of increasing antibiotic resistance. Alternative antibiotics are equally effective treatments, but may have a higher risk of increasing antibiotic resistance.
- Babies with a genetic variant in the mitochondrial MT-RNR1 gene (m.1555A>G) are at increased risk of profound bilateral deafness caused by damage to the ear (ototoxicity) if they have treatment with the aminoglycoside family of antibiotics, which includes gentamicin.
- Parents and families are already under considerable stress when a baby is admitted to a neonatal unit. When hearing loss occurs, it is a shock and can cause a mix of emotions. These emotions could be made worse if they knew a test existed that could have prevented this.
- Children with hearing loss have reduced access to spoken language, which affects their ability to communicate, as well as their social and emotional development. It can also affect their education and employment opportunities in the future.
- Currently available laboratory testing for the MT-RNR1 m.1555A>G gene variant cannot provide results quickly enough to inform antibiotic prescribing in babies with a suspected infection that need to be treated within 1 hour.
- Evidence presented to the independent NICE committee from the PALOH study showed no statistically significant difference in the time to antibiotic treatment between standard care and when using the Genedrive® MT-RNR1 ID Kit. This suggests that introducing the test will not delay the time it takes to administer antibiotics.

"The costs associated with hearing loss to the NHS are high, so driving an innovation like Genedrive into the hands of health and care professionals to enable best practice can also ensure that we balance the best care with value for money, delivering both for individuals and society as a whole."

- Mark Chapman, interim director of Medical Technology at NICE

Evidence Generation Recommendations

NICE EVA recommendations are conditional while more evidence is collected on the technology to address uncertainty in the evidence base. Once further evidence is collected, the guidance is reviewed to make a decision on the routine adoption of the technology.

Further evidence required on the following:

1. How the test affects time to antibiotics
2. How the test result affects antibiotic prescribing decisions
3. The technical performance and diagnostic accuracy of the test

Further evidence generation should ensure the test is implemented in centres with babies from different patient demographics and in a wide range of geographical regions to ensure equal access. It should also include smaller, non-specialist centres.

Important Points

1. Aminoglycoside-induced hearing loss has a major impact on the quality of life of children and their families.
2. Evidence suggests that the Genedrive® MT-RNR1 ID Kit quickly and accurately identifies babies with the MT-RNR1 m.1555A>G variant, who may be at risk of hearing loss if given aminoglycoside antibiotics. This will allow equally effective alternative antibiotics to be used instead.
3. There is currently no test available in the NHS that gives results quickly enough to inform decisions on antibiotic prescribing.
4. The long-term savings to the NHS associated with hearing loss and fitting cochlear implants could be substantial. Based on the early economic model, the Genedrive® MT-RNR1 ID Kit has the potential to be cost effective over a lifetime.

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