Resource impact summary report

Resource impact
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This summary report discusses the potential resource impact associated with the Genedrive MT-RNR1 ID Kit for detecting a genetic variant to guide antibiotic use and prevent hearing loss in babies. A local resource impact template has also been produced to support resource impact assessment for this early value assessment guidance. This approach is different from our normal resource impact assessment because evidence generation and data collection are needed to establish whether any of the resource benefits will be realised. It is acknowledged the evidence base is limited and the recommendations may change in future.

This early value assessment guidance covers the Genedrive MT-RNR1 ID Kit for detecting a genetic variant to guide antibiotic use and prevent hearing loss in babies.

As this is an early value assessment, the resource impact tools are not directing organisations to assess the cost of full rollout of these technologies. If there is an unmet need, this technology could be a solution, and organisations may therefore wish to identify potential resource impact.

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

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.

Currently available laboratory testing for m.1555A>G cannot provide results quickly enough to inform antibiotic prescribing in babies with suspected infection that need to be treated within 1 hour. It is assumed routine confirmatory laboratory testing of babies with a positive result will still be undertaken to confirm the real-world false positive rate.

The Genedrive MT RNR1 ID Kit (Genedrive) is a qualitative in vitro molecular diagnostic test for detecting the MT-RNR1 m.1555A>G variant. It is intended to be used by healthcare professionals in a near patient setting using a buccal (cheek) swab sample. The company says that the kit provides a result within about 26 minutes. This could help ensure that babies who have the m.1555A>G variant have alternative antibiotics and avoid irreversible, lifelong hearing loss caused by ototoxicity.

The prevalence of the MT-RNR1 m.1555A>G variant in the UK population is assumed to be 0.2% (Göpel et al. 2014). Babies with hearing loss are assumed to need bilateral cochlear implants.

Upfront costs include the Genedrive system (£4,995) and Bluetooth printer (£400). The lifespan of the equipment is assumed to be 6 years based on information provided by the company.

Clinical evidence suggests that the test quickly and accurately identifies babies with the MT-RNR1 m.1555A>G variant. Clinical experts said that there are equally effective alternative antibiotics that may be used instead of aminoglycosides; this would avoid the risk of lifelong hearing loss in babies with the variant and therefore have substantial benefits to those babies and their families. They noted that these alternatives are not used more widely because of concerns about antibiotic resistance. But because the variant is not common, only a small proportion of babies would have a positive test result and require alternative antibiotics. So, the risk of promoting antibiotic resistance is low.

Depending on current local practice, areas which may impact resources include:

- Costs of the technologies (Genedrive system and Bluetooth printer). Upfront costs of implementing the Genedrive test should be carefully considered by providers and commissioners. It noted that where possible, purchase options not associated with large capital investment costs should be explored for any conditional recommendation and real-world data collection.
- Staff workload may be increased if all babies who are going to be treated with antibiotics, or who are likely to be treated, are offered the point-of-care test. Staff will also need to be trained on how to use the test.

Implementing the guidance may have the following benefits:

- Preventing hearing loss will mean newborn babies will not require lifelong use of cochlear implants, won't experience the lifelong impacts of hearing loss, and won't require surgeries associated with treating severe or profound hearing loss.
- The costs associated with treating people with damage to their ears caused by antibiotics could be reduced.
- Better health outcomes and care experience.
- Hospitals currently not following recommendations from the NICE guideline on neonatal infection to use benzylpenicillin with gentamicin because of the risk of deafness now have a way to manage this risk and become compliant.

Neonatal services are commissioned by NHS England. Providers are NHS hospital trusts.

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