

Docket #: S19-051

Reformulated Hospital Gentamicin Reduces Risk of Hearing Loss

Researchers at Stanford have developed reformulated hospital gentamicin that reduces the side effect risk of hearing loss while maintaining antimicrobial activity. Gentamicin, an antibiotic used to treat life-threatening infections, is the second most commonly administered drug in the NICU, frequently used as a first line treatment in neonatal intensive care. A subset of patients experience hearing loss following treatment (incidence estimates vary between 2-20%). For the first time, researchers tested the antimicrobial and ototoxic (ear damaging) potencies of each of the individual components of hospital gentamicin to develop a new formulation that has shown reduced ototoxic side effects in rat cochlea. As gentamicin is produced by fermentation, it is a variable mixture, made up of five major components. By precisely remixing the more beneficial and less toxic components, the new formulation offers a more potent but safer drug of known and consistent composition. The extremely low cost of gentamicin (~\$2 / injection) allows for a margin of markup to recover the cost of producing this improved, life-saving drug.

Stage of Development

In vitro ototoxicity data has been collected on rat cochleae (the organ that is damaged when patients experience hearing loss). In vitro antimicrobial data collected to CSLI standard. Data collected on 40 strains of bacterial strains from four species: *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Escherichia coli* and *Staphylococcus aureus*. The chemical purification pathways are already developed for at least gram level work.

Applications

- Replacement for existing hospital gentamicin with reduced ototoxic side effects

Advantages

- Lower toxicity profile for the ear
- Formulation is suitable for straight-to-humans studies
- Removes the most toxic as well as the least bactericidal components
- Higher manufacturing cost would be offset by potency and safety
- Can be produced in high volumes, with consistent composition

Publications

- Mary E. O'Sullivan et al. [Dissociating antibacterial from ototoxic effects of gentamicin C-subtypes](#) *PNAS* December 2020.

Innovators

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