

Ekaterine Tortladze, Georgia Funding CI: a medical device or assistive technology?

- Ekaterine Tortladze is the mother of a 25 year old young woman with a hearing loss.
- She founded the Aures Foundation, a nongovernmental organization that deals with hearing issues in Georgia.
- She is a member of WHD core group at WHO, representative of Lehnhardt Stiftung in Georgia, and part of Advocacy Committee of the Coalition for Global Hearing Health.



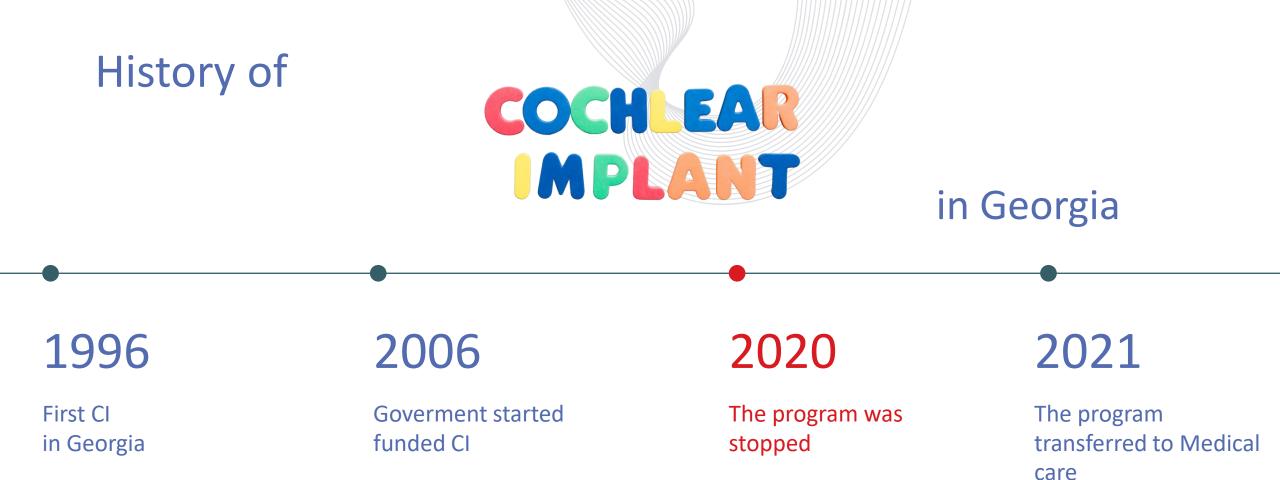
Cochlear implant is one of the most successful of all neural prostheses developed to date (WRH, page 100)



Their use to lessen the impact of deafness and hearing loss has been limited with considerable variation and a lack of take up of those who could benefit, including in high income countries.







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Is CI priority in countries like Georgia?



Long History

Government covers

- CI
- Fitting sessions
- Rehabilitation therapy after CI (144 hour)



- The adults are always out of support
- Rehabilitation therapy starts only after CI
- No support for families
- No support with expendable materials
- No chance to replace or upgrade Speech Processor
- In 2020 CI program was stopped



IS it a MEDICAL DEVICE or ASSISTIVE TECHNOGY?

FDA Regulation of Cochlear Implants

Cochlear implants are designated as Class III devices, meaning they receive the highest level of regulatory scrutiny.

This is because they are surgically implanted, which increases health risk.

But how about external part?

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Assistive products: (WHO document)

Any external product (including devices, equipment, instruments or software), especially produced or generally available, the primary purpose of which is to maintain or improve an individual's functioning and independence, and thereby promote their well-being. Assistive products are also used to prevent impairments and secondary health conditions.

Priority assistive products:

Those products that are highly needed, an absolute necessity to maintain or improve an individual's functioning and which need to be available at a price the community/state can afford



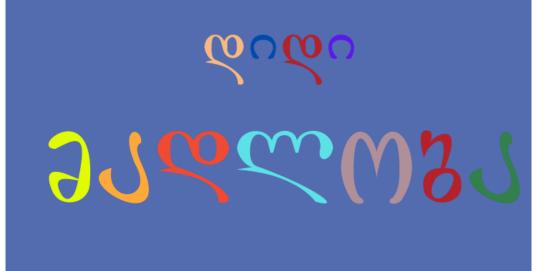
Provision of Speech Processor will be much easier if

> in countries will exist Assistive Technology Priority Lists

Some exciting news.....!!









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