

Dr. Markus Meis

Hörzentrum Oldenburg gGmbH

Methodological Implications of the Minimal Clinically Important Difference in Questionnaires Used in Audiology

The effectiveness of interventions in the field of hearing aid and cochlear implant provision is primarily demonstrated through speech audiometric procedures under ideal conditions; see also the HilfsM-RL (2025) regarding hearing aids.

Since the introduction of the MDR in 2017, manufacturers have been required to demonstrate effectiveness not only in the laboratory but also in everyday life through real-world data. Key data sources include questionnaire-based methods and everyday assessments conducted by the customers/patients themselves.

Rulings by the Federal Social Court in June 2025 regarding reimbursement for hearing aids underscore the importance of subjective assessments by people with hearing impairments when “significant benefits in everyday use” can be demonstrated by devices exceeding the fixed reimbursement limit.

Currently, there are no consensus-based methods for determining the minimal clinically important difference (MCID) in questionnaires as Patient-Reported Outcome Measurements (PROMs).

Based on developments over the past 10 years, we present an anchor-based methodological framework to determine minimally clinically relevant thresholds for hearing care and audiology on a case-by-case basis in the future.