FIRST DRAFT

BILATERAL AND UNILATERAL HEARING-AID FITTINGS

Background

There is a widespread consensus amongst professionals that where a hearing impaired person has two impaired, but aidable, ears, that there are potential benefits from bilateral, as opposed to unilateral, hearing aid fittings. In terms of policy and practice, patients would be offered the choice between bilateral and unilateral fittings, informed of the knowledge of the potential benefits and penalties in their own particular clinical circumstances. In the United States where market forces are dominant, surveys show that a substantial majority of fittings are indeed bilateral. In other healthcare delivery systems where regulatory and funding bodies require an evidence base to formulate policy and practice, the penetration of bilateral fittings is in general somewhat lower.

While there are numerous demonstrations of the potential benefits of bilateral fittings in constrained laboratory settings on tests of speech intelligibility in noise, there are no robust randomised control trials of bilateral versus unilateral fittings in the domains of self-reported disability, handicap and health-related quality of life. Thus regulatory agencies have the opportunity to restrict funding for bilateral fittings, and in some countries are doing so increasingly. The mismatch between the professional consensus and current policies restricts the potential effectiveness of current hearing aid services.

A Potential Way Forward

We contended that the issues regarding bilateral fittings are pervasive and not restricted to any particular country or healthcare delivery system. The existence of a multi-site, multi-nation robustly designed, randomised control trial of bilateral versus unilateral fittings would furnish the audiological community with convincing evidence of the potential advantages, and limitations, of bilateral fittings. Such a trial, with common design criteria outcomes and analyses, would be a more effective vehicle to influence policy than heterogeneous enterprises in different clinical settings. The objective would be to look to investigate the benefits of bilateral versus unilateral fittings and to identify the dimensions of candidature which influence both the benefits and penalties of such bilateral management. The trial would be designed to include sets of outcomes and predictors that were common across nations and sites and would include the most sensitive and appropriate outcomes and predictors as identified by current research (for example, recent results demonstrating benefits of bilateral fittings in domains other than traditional static segmental speech intelligibility).

Planning a Randomised Control Trial

If a randomised control trial (RCT) is to carry weight with regulatory authorities, it has to be conducted with scientific rigour and be recognised as

independent of vested interests. The International Collegium of Rehabilitative Audiology (ICRA) has recently formed a working group (consisting of Arlinger, Kiessling, Verschuure, Wouters and Gatehouse – with industry advice from Naylor) to investigate the viability of a comprehensive RCT. The preliminary plans are for clinical settings in Sweden, Germany, The Netherlands, Belgium and the United Kingdom with the design common across these systems, but adapted in detailed implementation to take account of the differing practice and funding arrangements in the diverse settings. We envisage national project leaders under the overall co-ordination of Arlinger. ICRA are in the process of securing funding for the planning phase which is scheduled to be complete by the end of 2005. The planning phase includes a preliminary engagement with potential funding avenues and this document represents part of that engagement. The RCT will be a between-groups allocation to initial bilateral versus unilateral fitting, with a subsequent cross-over element to facilitate a within-subject contrast. The experiment aims to be statistically powered so that each clinical setting can be analysed independently but then contrasted and amalgamated at a later date. The planning process aims to construct a comprehensive application and potential funding route for consideration by the end of 2005.

Elements of a Randomised Control Trial

The planning phase has developed a preliminary specification for the trial including dimensions of outcome, dimensions of candidature and aspects of statistical power. Although subject to development, the current design implies approximately 400 volunteer subjects to be entered in each clinical setting in the twelve- month recruitment period into the trial. Outcome dimensions include self-reports of disability and handicap (extended to the novel dimensions outwith static speech intelligibility), sensitised measures of health utility to access health-related quality of life, and measures of speech intelligibility. Predictor dimensions include the abnormal binaural psycho-acoustics accompanying SNHL, auditory ecology, manual dexterity, cognition and patient attitude and expectations.

The Proposal

The proposal is to design, fund and conduct a multi-site, multi-nation, randomised control trial of bilateral versus unilateral hearing aid fittings, to be designed by the end of 2005 and to be completed and decimated by the end of 2007. This document contains the background rationale and characteristics of such a trial as part of the process of the ICRA working group engaging with interested parties and potential funding avenues.