Appareils auditifs en Belgique: Health Technology Assessment

KCE reports 91B

Federaal Kenniscentrum voor de Gezondheidszorg
Centre fédéral d'expertise des soins de santé
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PREFACE

En vieillissant, la probabilité de subir une perte d'audition augmente. Plus de la moitié des personnes entre 61 et 70 ans souffrent d'une manière ou l'autre d'une réduction auditive, ils sont plus de 80% à connaître cet inconfort après 70 ans.

Les conséquences de cette déficience ne se limitent pas au '*Pouvez-vous répéter, s'il vous plaît?*'. Une réduction, même légère, de l'acuité auditive entraîne d'emblée une restriction considérable de la capacité d'une personne à communiquer et à s'exprimer. Converser entre amis ou au supermarché, conduire une voiture, interagir avec autrui tout au long de la journée… tout devient beaucoup plus difficile.

Si il existe bien des appareils auditifs pour pallier, au moins partiellement, ces différents problèmes, il apparaît que ces appareils auditifs ne sont utilisées que par une minorité de malentendants, alors que nombre d'entre eux pourraient bénéficier de leur remboursement. Sur ce plan, la Belgique semble être à la traîne par rapport aux autres pays. Faut-il en trouver la raison dans la piètre efficacité de ces appareils? Dans leur prix ou dans la modicité de leur remboursement? Les critères de remboursement sont-ils adéquats ou, autrement dit, faut-il être un peu, très ou complètement dur de la feuille pour obtenir le remboursement de son appareil auditif ?

Le présent rapport *'Health Technology Assessment'* ne résout pas toutes ces questions, mais espère inciter à la réflexion et promouvoir le débat entre les patients, les prestataires de soins, les décideurs et les autres parties prenantes.

Gert Peeters
Directeur général adjoint a.i

Jean-Pierre Closon
Directeur général a.i.

Résumé

INTRODUCTION

La perte d'audition est l'une des affections chroniques les plus fréquentes et est fortement associée au vieillissement. Il ressort d'études réalisées à l'échelle internationale que plus de la moitié de toutes les personnes âgées de 61 à 70 ans, et plus de 80% des plus de 70 ans, souffrent d'un déficit auditif d'intensité variable. Bien entendu, la prévalence exacte est fonction des critères et définitions précis utilisés, qui vont de la perte auditive légère aux déficits graves et invalidants. Toutefois, il ne fait aucun doute que la déficience auditive a un impact sociétal considérable puisqu'elle affecte la qualité de vie des citoyens, principalement des seniors.

Il est possible d'atténuer partiellement une incapacité auditive grâce à un appareil auditif. Cela étant, des données belges montrent qu'une faible proportion seulement de la population éligible pour le remboursement d'un appareil auditif (AA) en acquiert effectivement un. Il existe une large palette d'appareils auditifs de niveaux de complexité et, par conséquent, de prix variables. Il est peu probable que l'évolution technologique s'arrête puisque les entreprises mettent désormais exclusivement au point des AA numériques et que les modèles analogiques vont vraisemblablement disparaître. Toutefois, il convient de souligner le fait que la valeur ajoutée des appareils auditifs plus complexes et plus coûteux reste souvent non étayée.

Le remboursement des appareils auditifs en Belgique se fonde sur un montant forfaitaire fixe de pratiquement 500€ pour les appareils unilatéraux et d'environ 950€ pour les appareils auditifs bilatérales. Ce remboursement correspond au niveau le plus bas en termes de complexité et de prix pour les appareils auditifs disponibles sur le marché belge. Les dépenses globales de l'Institut national d'assurance maladie-invalidité (INAMI) en appareils auditifs pour la population belge adulte sont d'environ 20 millions € par an, pour approximativement 40 000 appareils.

L'objectif du présent rapport "Health Technology Assessment" sur les appareils auditifs consiste à examiner les données probantes en termes d'efficacité et de coût efficacité des différentes caractéristiques des appareils auditifs, à dépeindre le marché des appareils auditifs en Belgique et dans d'autres pays. Il vise également à décrire les critères et les règles de remboursement dans divers pays et à évaluer l'utilisation des appareils auditifs en Belgique, leur remboursement et les implications budgétaires pour notre pays, tant à l'heure actuelle que dans un avenir proche. La présente analyse est circonscrite aux appareils auditifs conventionnelles non implantées éligibles pour un remboursement par l'assurance maladie belge. En effet, ce sont ces modèles conventionnels qui représentent le traitement de premier choix de la presbyacousie, à savoir la perte d'audition associée à l'âge.

Le but ultime du présent rapport consiste à évaluer si la situation actuelle en matière d'offre et de remboursement des appareils auditifs en Belgique est optimale ou perfectible. Les constats émanant du présent rapport contribueront à la formulation de recommandations politiques ayant pour objectif de définir des pratiques de remboursement équitables et rentables.

METHODES

Aux fins du présent "Health Technology Assessment", diverses approches analytiques ont été utilisées :

- Un examen de la littérature concernant l'efficacité clinique et le rapport coût efficacité des appareils auditifs afin de décrire la situation actuelle en matière de technologie pour les appareils auditifs.
- Une analyse approfondie du marché des appareils auditifs à l'échelle globale et belge, dans le but de se pencher sur les facteurs économiques en jeu qui seraient susceptibles d'interagir avec les politiques de remboursement des pouvoirs publics.
- Un tour d'horizon des choix politiques internationaux en matière de remboursement des AA et des comparaisons de prix afin d'inspirer les décideurs belges.
- Un examen des implications budgétaires actuelles et futures.

RESULTATS

LITTERATURE SCIENTIFIQUE

Efficacité clinique

En dépit d'une abondante littérature sur les appareils auditifs, la littérature actuellement disponible à propos de leur efficacité clinique ne permet pas de formuler des recommandations basées sur des données probantes. En effet, seul un petit nombre de documents fournissent des preuves de niveau élevé émanant de RCT ("randomized controlled trials" ou essais cliniques randomisés) et ces quelques études sont elles-mêmes caractérisées par des biais méthodologiques majeurs. De surcroît, les études en question sont très hétérogènes, tant au niveau des méthodes que des paramètres testés, et ne permettent pas de réaliser des méta analyses pertinentes.

Les résultats de notre examen sont cohérents par rapport à des exercices similaires antérieurs. Nous observons un différentiel entre les tests objectifs réalisés en laboratoire d'audiologie et les questionnaires portant sur la qualité de vie en relation avec l'audition ou la santé qui étaient également rapportés dans d'autres examens de la littérature. En général, ce sont les appareils auditifs non linéaires qui recueillent la préférence par rapport aux modèles à amplification linéaire, tandis que les appareils numériques sont préférés aux analogiques, et ce en dépit du fait que les preuves de leur supériorité soient très faibles et que la plupart de ces prevues ne soient apportées qu'à travers des questionnaires et non pas grâce à des tests audiologiques objectifs. Les appareils auditifs directionnelles donnent de meilleures performances auditives que les AA omnidirectionnelles, bien que l'environnement acoustique a une influence énorme sur ces performances. Tous les articles se sont efforcés d'étudier un paramètre spécifique et ont montré que les caractéristiques plus complexes sont souvent mieux notées par les patients que les caractéristiques moins complexes. Par ailleurs, dans les études, on a également observé une variation importante au niveau de l'évaluation d'efficacité par rapport à des caractéristiques spécifiques du patient, ayant trait non seulement à l'audition (âge, gravité ou durée de la perte auditive) mais aussi au mode de vie et au cadre de vie.

Dans le présent rapport, nous décrivons et évaluons les améliorations majeures dans la technologie des AA. Il est intéressant de souligner le fait que les plus importantes parmi ces caractéristiques sont déjà présentes dans ce que l'on appelle les appareils auditifs dites de "moyenne technologie" disponibles déjà à partir d'environ €1400.

Coût efficacité

Le rapport coût efficacité des appareils auditifs n'a pas pu être démontré dans les quelques études qui ont été réalisées. La raison principale en étant que les questionnaires "Qualité de vie" qui ont été utilisés ne montraient pas d'impact sur la qualité de vie générique. Un résultat qui est peut-être du au choix de l'instrument EuroQol, dans lequel l'audition n'est pas mesurée en tant que dimension spécifique, par opposition à, par exemple, l'instrument HUI3. Compte tenu des limitations des études disponibles en termes de qualité et de pertinence pour notre recherche, aucune conclusion fondée sur des données probantes ne peut être tirée à propos du rapport coût efficacité des appareils auditifs.

ANALYSE DU MARCHE

Les informations clés étant souvent confidentielles, réaliser une analyse de marché pour les appareils auditifs était un véritable défi. Le marché global des fabricants d'appareils auditifs s'est modérément concentré durant les années 90 et a même subi une concentration continue depuis, à travers des fusions et achats. A l'heure actuelle, six fabricants représentent 90% de toutes les appareils auditifs sur le marché belge.

On n'observe pratiquement aucune concurrence au niveau des prix sur le marché de détail belge. Les prix de vente proposés pour les AA sont publiés par les importateurs et même si les distributeurs ont toute liberté de les vendre à un autre prix, ce dernier ne varie pas entre les différents distributeurs. Les AA les plus vendus ne sont pas les moins chers, mais ceux dont le prix dépasse les 1000€, soit plus du double par rapport au remboursement forfaitaire défini.

Une telle situation est due à plusieurs facteurs. Du côté de l'offre, le marché est un oligopole, ce qui entrave dans une mesure considérable le jeu des mécanismes normaux du marché libre. De surcroît, les audioprothésistes reçoivent directement une partie du prix des AA, la proportion exacte de la somme perçue restant confidentielle. Du côté de la demande, il importe de comprendre que la demande est relativement inélastique au prix, car les appareils auditifs sont perçues comme des biens de nécessité et que les patients sont mal placés pour apprécier la relation entre les différentiels de prix et les différentiels d'efficacité.

En conséquence, le marché des appareils auditifs mérite de faire l'objet d'un examen minutieux de la part des pouvoirs publics afin de garantir son fonctionnement correct.

COMPARAISONS INTERNATIONALES

Politiques de remboursement

En Belgique, les patients qui souffrent d'une incapacité auditive doivent consulter un médecin ORL (oto-rhino-laryngologiste) afin d'obtenir une prescription pour un test d'appareil auditif. Avec ce document, le patient se rend chez un audioprothésiste qui effectue une série de tests audiologiques et lui fournit un appareil auditif pour une période d'essai. Après deux semaines, le patient retourne chez son ORL pour une évaluation. Si le patient est satisfait de son appareil auditif, le spécialiste ORL lui délivre une ordonnance qui lui donne le droit de percevoir le remboursement forfaitaire. Afin d'être éligible pour le remboursement, la perte auditive doit être d'au moins 40 dB à 1, 2 et 4 KHz, avec certaines exigences complémentaires en termes de gain au niveau de la reconnaissance de la parole avec l'appareil auditif.

Les conditions de remboursement varient fortement entre les huit pays européens comparés dans le présent rapport. Dans des pays comme le Danemark, le Luxembourg et le Royaume-Uni, les appareils auditifs sont remboursées à 100%, alors que dans d'autres pays comme l'Espagne, aucun remboursement n'est prévu. Il convient de souligner le fait que les trois pays précités restreignent le choix des appareils auditifs proposées qui sont remboursées par les pouvoirs publics, à travers une liste des appareils auditifs éligibles pour un remboursement dressée soit par reconnaissance de produit (Luxembourg), soit par soumissions publiques (Royaume-Uni et Danemark).

Parmi les pays dotés de systèmes de remboursement forfaitaires (le montant devant couvrir à la fois l'appareil et la fourniture de services), la Belgique rembourse un montant forfaitaire similaire à celui de pays limitrophes comme l'Allemagne et les Pays-Bas, mais nettement supérieur au remboursement en France. Si le niveau général de remboursement en Suisse semble plus généreux qu'en Belgique, le système est toutefois moins favorable pour les personnes retraitées par rapport aux sujets plus jeunes.

Certaines règlementations spécifiques applicables dans d'autres pays pourraient constituer une source d'inspiration pour les décideurs belges. Ainsi, l'essai par le patients de plusieurs appareils, y compris des modèles moins onéreux qui ne demanderaient en fin de compte aucune quote-part du patient, est obligatoire en Allemagne et en Suisse. D'autres pays, tels que le Royaume-Uni et le Danemark, sont dotés de procédures de soumission publique ou bien font effectuer des tests par un organisme public (Luxembourg). La Suisse possède quant à elle un système de remboursement forfaitaire scindé en deux, une part couvrant l'AA proprement dit et l'autre les services de mise au point de l'appareil pour le patient. Autre élément intéressant : l'Allemagne possède un système de commande par envoi postal direct d'appareils à partir des fabricants/assembleurs vers le cabinet de l'ORL.

Enfin, dernier élément méritant d'être épinglé et qui pourrait nous inspirer : en Suisse, pour déterminer le traitement qui convient le mieux au patient, le régime de remboursement des appareils auditifs se fonde sur une échelle à trois niveaux correspondant à la gravité de l'atteinte du patient et prend en considération les facteurs psychosociaux. Un rapport datant de 2007 réalisé par EFK, une entité publique suisse responsable de la surveillance des finances publiques, préconise l'abolition de ce système de remboursement à trois niveaux qui est entré en vigueur le premier avril 1999, car le système en question apparaît comme "trop onéreux et mal conçu". Il semblerait que ce système soit à l'origine d'une tendance haussière au niveau de la gravité rapportée de l'atteinte des patients, avec à la clé une augmentation de la part budgétaire des dépenses en appareils auditifs pour la catégorie de patients la plus élevée. Leur pourcentage est passé de 36 % en 2001 à 50 % en 2005. De surcroît, le rapport affirme qu'il n'est pas possible de déterminer une corrélation directe entre la gravité du cas du patient et les coûts de traitement nécessaires. En conséquence, l'EFK propose de remplacer le système suisse actuel par un régime forfaitaire uniforme, autorisant des dérogations au cas par cas, en fonction du dossier personnel de chaque patient.

Niveaux de prix constatés

Une comparaison de prix a été effectuée entre la Belgique et sept autres pays pour des appareils ayant été identifiés comme étant représentatifs du marché belge. De telles interprétations de prix internationales doivent être considérées avec une certaine prudence, car il arrive que ces prix comprennent des périodes de garanties, des accessoires, des services, etc. qui varient.

Abstraction faite de ces réserves d'ordre méthodologique, la comparaison montre une forte variation de prix entre les pays. Le coefficient de variation moyen pour les produits comparés dans l'échantillon de pays est de 21 %. Quant au facteur d'écart moyen entre les prix les plus bas et les plus élevés, il se situe autour de 1.8.

Des 46 comparaisons de produits spécifiques, les prix de ventes belges étaient plus élevés 37 fois. Si l'on compare les pays, ce constat est encore plus frappant : par rapport au Danemark (les prix belges étaient plus élevés pour 9 produits comparés sur 10), aux Pays-Bas (7/8), à la Suisse (6/7), au Royaume-Uni (5/5) et à la France (5/6). Mais, il faut souligner que pour la Suisse, le prix ne couvre que l'appareil proprement dit et pas les services de mise au point. La part du remboursement couvrant l'appareil est inférieure pour la plupart des patients suisses par rapport au forfait belge tandis que le montant belge comprend les services de l'audioprothésiste.

Interaction entre le niveau des prix et la politique des pouvoirs publics

Les comparaisons possibles pour les appareils à bas prix étaient trop peu nombreuses pour valider ou invalider l'hypothèse selon laquelle des honoraires forfaitaires entraîneraient un alignement des prix pour ce segment de la catégorie produits.

Cela étant, les prix des AA affichent une volatilité surprenante pour un produit à ce point normalisé émanant d'un seul producteur. Un constat qui fait naître ce soupçon que les prix seraient davantage influencés par des facteurs de nature politique plutôt que par les mécanismes normaux du marché libre. Ceci expliquerait le fait que dans les pays qui achètent également les appareils auditifs via des soumissions publiques, les prix sont souvent inférieurs par rapport à ceux pratiqués en Belgique.

EXPLORATIONS BUDGETAIRES

En 2006, le budget global de l'INAMI pour les appareils auditifs non implantées se montait à 20 millions €, soit 0.1% du budget de remboursement des soins de santé en Belgique. Les appareils auditifs chez les adultes représentent 95 % de ce budget. Les femmes constituent 53 % des utilisateurs d'appareils auditifs, davantage que ce l'on pourrait escompter si l'on compare la prévalence des déficits auditifs et la démographie.

Le nombre annuel d'appareils auditifs bilatérales remboursées annuellement a augmenté de 25 % entre 1995 et 2005 pour atteindre environ 15 000, ce qui correspond à 30 000 dispositifs. D'autre part, le nombre annuel d'appareils auditifs unilatérales remboursées a légèrement diminué, jusqu'à quelque 10 000 appareils. Au total, les appareils auditifs bilatérales représentent les trois quarts des appareillages chez l'adulte. En Belgique, on peut observer une ligne de partage entre l'est et l'ouest du pays en ce qui concerne les schémas d'utilisation. Ainsi, la partie orientale du pays a recours de manière nettement supérieure aux appareils auditifs bilatérales.

En se fondant sur un modèle de simulation alimenté par les données d'une étude épidémiologique de grande envergure au sein de la population générale norvégienne et portant sur 50 000 personnes, notre étude a permis de se rendre compte que la population belge âgée de 20 à 89 ans et éligible pour un appareil auditif devrait augmenter d'environ 700 000 en 2006 à plus de 1 million en 2030. Approximativement 50 % de ces patients répondent également aux critères supplémentaires pour les appareils auditifs bilatérales. Après correction de ces différences de taux de consommation relative observées empiriquement entre les groupes de patients en fonction de l'âge et du sexe, le budget actuel de l'INAMI devrait, selon les projections, augmenter de 46 % en 2030, ce qui correspond à un taux réel de croissance à long terme de 1.6%. Il convient de souligner le fait qu'il s'agit d'extrapolations budgétaires statiques fondées sur des observations datant de 2006 et que celles-ci ne reposent que sur l'évolution budgétaire la plus probable en se fondant uniquement sur les changements démographiques.

Des simulations ultérieures indiquent qu'une modification des seuils d'audition minima actuellement appliqués induit un changement de taille au niveau du nombre des populations éligibles. De surcroît, la taille de la population éligible et la part représentée par les patients plus jeunes (moins de 60 ans) sont extraordinairement sensibles à des modifications des fourchettes de fréquences testées. Un constat qui suscite des interrogations à propos de l'équité au sens général, notamment, une égalité d'accès au marché de l'emploi, etc.

CONCLUSION

Les constats extraits de la littérature scientifique actuellement disponible n'ajoutent pas grand-chose au débat politique sur le remboursement des appareils auditifs. À l'heure actuelle, une incertitude subsiste toujours à propos d'une meilleure pratique fondée sur des données probantes, tant efficace que coût efficace. Une situation que semble confirmer l'expérience des décideurs politiques suisses qui ont finalement conclu que leur cadre politique très pointu, associant la gravité de l'état du patient à un remboursement "sur mesure" de l'appareil auditif, n'avait en fin de compte pas atteint son objectif initial.

Pour ces raisons, un rehaussement des niveaux de remboursement globaux actuels ne sera pas nécessairement générateur de véritables avantages additionnels pour les patients. Les niveaux de remboursement belges actuels sont similaires à ceux appliqués aux Pays-Bas, légèrement inférieurs par rapport à l'Allemagne et supérieurs par rapport à la France. Par conséquent, il n'est pas possible de conclure que les niveaux belges sont nettement inférieurs à ceux pratiqués par nos pays voisins dotés de systèmes de remboursements forfaitaires.

Certains éléments indiquent que le niveau de prix des appareils auditifs est en partie influencé par des facteurs liés à la politique de remboursement et ne sont pas uniquement tributaires des mécanismes normaux du marché libre. Un tel constat signifie qu'il y a sans doute matière à amélioration et que certains systèmes de remboursement en place dans d'autres pays pourraient nous aider à créer un marché plus transparent des appareils auditifs.

Les critères de remboursement appliqués actuellement en Belgique sont relativement sévères par rapport à d'autres pays et une option éventuelle pourrait être de les modifier. Un tel changement permettrait à davantage de personnes en âge d'être actives sur le marché de l'emploi d'avoir accès aux appareils auditifs.

Ce type de mesures politiques devrait faire l'objet d'un débat public. Idéalement, ce débat devrait être enrichi par des recherches ultérieures sur les avantages réels des appareils auditifs à différents degrés de déficit d'audition. Par ailleurs, il faudrait se pencher sur les avantages relatifs de l'appareillage unilatéral par rapport aux appareils auditifs bilatérales, car on observe des variations d'utilisation remarquables tant au niveau national, dans les différentes régions du pays, qu'international.

RECOMMENDATIONS

TRANSPARENCE POUR LE PATIENT

- La relation entre le prix et la complexité de l'appareil auditif est souvent floue. À cette fin, la classification actuelle en quatre catégories utilisée par les fabricants et les importateurs est trop brute. L'échelle de complexité développée dans le présent rapport devrait être mise au banc d'essai afin de voir si elle permet une classification plus transparente.
- Les patients devraient avoir la possibilité d'essayer plusieurs appareils auditifs, y compris les moins chères pour lesquelles aucune intervention personnelle n'est exigée. Le but étant de leur permettre de poser le meilleur choix en fonction de leur situation spécifique. Le choix final ne devrait pas uniquement se fonder sur les résultats audiométriques, mais également sur des questionnaires de satisfaction du patient dans différents environnements acoustiques et en fonction des exigences de ce dernier en matière de mode de vie et d'audition.
- La prescription d'une aide auditive suppose que le prescripteur a suivi et suit une formation spécifique continuée l'informant sur les caractéristiques des aides auditive et leur réglages, sur les examens nécessaires pour évaluer le gain prothétique et sur les modalités de comparaison d'aides auditives pour que le choix de l'aide auditive corresponde au meilleur rapport qualité/coût pour le patient. Cette formation spécifique doit être organisée et réalisée par des scientifiques et cliniciens indépendants des firmes commercialisant les aides auditives.

PRIX ET REMBOURSEMENT

- Une désagrégation de l'honoraire pour le placement et la mise au point par l'audioprothésiste, du prix de l'appareil auditif proprement dit, augmenterait la transparence, par rapport à la situation actuelle où l'audioprothésiste reçoit une fraction du prix de l'appareil auditif vendue par lui, un système qui introduit un incitant à vendre des appareils auditifs à prix élevés.
- Une soumission publique pour les appareils auditifs dotés des caractéristiques techniques les plus importantes, comme la pratiquent certains pays européens, pourrait fournir un cadre de référence financier pour les appareils auditifs de niveau technologique satisfaisant, disponibles sans quote-part du patient. Une telle approche pourrait impliquer une révision du montant du remboursement forfaitaire pour les appareils auditifs.

Scientific Summary

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ABBREVIATIONS AND LEXICAL CONVENTIONS

AGC	Automatic Gain Control
AGCI	Automatic Gain Control of the Input
AGCO	Automatic Gain Control of the Output
AI	Assurance Invalidité (Switzerland)
AIAD	Amsterdam inventory for Auditory Disability and Handicap (AIAD)
ALDQ	Auditory Lifestyle and Demand Questionnaire
APHAB	Abbreviated Profile of Hearing Aid Benefit
Audioprothesist	Term applied throughout this report to indicate health professionals involved in hearing loss diagnostic testing and hearing aid device fitting, selling and post-sales servicing. As such this term covers several professional groups in various countries: Gehörakustiker, Audioprothésistes, Audiciens, Audiologists, etc.
AVC	Automatic Volume Control
AVS	Assurance Vieillesse et Survivants (Switzerland)
AWIPH	Agence Wallonne pour l'Intégration des Personnes handicapées (Belgium)
BILL	Bass Increase at Low Level
BTE	Behind The Ear
CI	Confidence Interval
CIC	Completely In the Canal
CL	Compression Limitation
CMU	Couverture Maladie Universelle (France)
COSI	Client-Oriented Scale of Improvement
CPT-AMA	Current Procedural Terminology (CPT) from the American Medical Association (AMA)
dB	Decibel
dB HL	Clinical unit using the hearing thresholds of young normally hearing subjects as reference
dB SPL	A physical measure of sounds intensity using a reference of 20 µ Pascal; dB = log P/20 µ Pascal
DR	Dynamic range. *'Dynamic range of audition'* or *'hearing dynamic range'* or *'auditory dynamic range'* are all synonyms (= the intensities differences between the perception thresholds and the discomfort levels for one specific frequency).
DVARS	Direct visual analogue rating scale
EAR scale	Effectiveness of Auditory Rehabilitation scale
EEC	External Ear Canal
EFK	Eidgenössische Finanzkontrolle (Switzerland)
ENT (physician)	Ear, Nose and Throat (physician); this term has been maintained throughout the report to designate physicians specialized in Otorhinolaryngology, in keeping with applying equivalents in various countries ("médecin spécialiste ORL (Otorhinolaryngology)", "KNO(Keel-Neus-Oor)-arts", "Facharzt für HNO (Hals-, Nasen- und Ohrenheilkunde)", etc.)
EQ-5D	EuroQol 5 dimensions (valuation tool for general Quality of Life)
EU	European Union
FB	Feedback
FPS	Federal Public Service (Ministry, Belgium), same as FOD/SPF: Federale Overheids Dienst/Service Public Fédéral)
GHABP	Glasgow Hearing Aid Benefit Profile
GHSI	The Glasgow Health Status Inventory

GP	General Practionner
HA	Hearing Aid(s)
HAPI	Hearing Aid Performance Inventory
HAPQ	Hearing Aid Performance Questionnaire
HHI	Herfindahl-Hirschman Index
HHIE	Hearing Handicap Inventory for the Elderly
HHIE-S	Hearing Handicap Inventory for the Elderly - Shortened
HI	Hearing Impaired
HL	Hearing Loss
HRQoL	Health-Related Quality of Life
HTA	Hearing Threshold Average
HTL	Hearing Threshold Level
HUI3	Health Utilities Index 3 (valuation tool for general Quality of Life)
Hz	Hertz = measure's unit of a sound's frequency (number of cycles per second)
ICER	Incremental Cost-effectiveness Ratio
IOI-HA	International Outcome Inventory for Hearing Aids
ITC	In The Canal
ITE	In The Ear
LPP	Liste des Produits et Prestations remboursables (France)
MPO	Maximal Power Output
NHS	National Health Service (UK)
NIHDI	National Institute for Health and Disability Insurance (RIZIV/INAMI) (Belgium)
PC	Peak Clipping
PHAB	Profile of Hearing Aid Benefit
PHAP	Profile of Hearing Aid Performance
PIADS	Psychosocial Impact of Assistive Devices Scales
PPP	Purchasing Power Parity
QALY	Quality Adjusted Life Year
QoL	Quality of Life
QWB	Quality of Well-Being Scale
RCT	Randomized Controlled Trial
RIZIV/INAMI	National Institute for Health and Disability Insurance (NIHDI) – Rijksinstituut voor ziekte- en invaliditeitsverzekering/Institut national d'assurance maladie-invalidité (Belgium)
S/N (ratio)	Signal-to-Noise (ratio) (=the difference between the signal and noise intensities presented simultaneously during speech tests in noise)
SADL	Satisfaction with Amplification in Daily Life
SAP	Service AudioPhonologique (Luxemburg)
SDS	Speech Discrimination Score
SF-36	Medical Outcome Study Short Form 36
SF-6D	Short Form 6 dimensions, a new instrument derived from the Medical Outcomes Study Short Form 36
SHAPI	Shortened Hearing Aid Performance Inventory
SNHL	Sensorineural hearing loss
SPIN	Speech Perception In Noise
SPL	Sound Pressure Level

SRT	Speech Reception Threshold
TILL	Treble Increase at Low Level
TIPS	Tarifs Interministériels des Prestations Sanitaires (interministerial tarifs for health care interventions) (France)
UK	United Kingdom
UPFI	Union des Producteurs Phonographiques Français Indépendants (France)
USA	United States of America
VAPH	Vlaams Agentschap voor Personen met een Handicap (Belgium)
VAS	Visual Analogue Scale
WDRC	Wide Dynamic Range Compression.
WHO-DAS II	World Health Organization's Disability Assessment Scale II

1 INTRODUCTION

1.1 SCOPE AND PURPOSE OF THIS REPORT

This report tries to answer a question from the National Institute of Health and Disability Insurance (NIHDI - RIZIV/INAMI) about a possible increase of the hearing aids (HA) reimbursement for adults suffering from hearing loss (HL). Currently, the reimbursement is a lump sum of approximately €500, whatever the price of the HA.

To answer this question, the following topics must be clarified:

- What is the evidence available in the literature in term of effectiveness and cost-effectiveness? (chapter 2 and 3)
- Is there a relationship between HA prices and HA technological characteristics? (chapters 2, 4 and 5)
- Is there a relationship between HA technological characteristics and HL improvement and/or quality of life? (chapters 2-4)
- What is the impact of HA technological characteristics, HA price, and HA benefits on the cost-effectiveness ratio? (chapters 3-4)
- How to describe the hearing aids market in terms of HA availability, HA price, organization of HA sales, the number of HA reimbursed by NIHDI? (chapters 4-7)
- What are the HA reimbursement modalities and HA prices in other countries? (chapter 6)
- What is the potential impact of HA reimbursement modifications on the budget? (chapter 7)

Hearing loss is one of the most common chronic illnesses, especially in elderly persons. It adversely affects physical, cognitive, behavioural and social functioning, as well as general quality of life (QoL), and has been linked to depression and dementia. Numerous studies have demonstrated that hearing aids provide significant benefit for a wide range of sensorineural hearing loss conditions. A large variety of hearing aids (HA) are available on the market. With advances in hearing aid technology resulting in an array of products with varying features and cost, more information about the relative effectiveness of different hearing aids is needed to help clinicians and to provide informed treatment recommendations.

In a context of a relatively fixed overall budget for health expenses, it is also important to determine the most cost-effective HA, given that the number of potential beneficiaries will continue to increase with the ageing of population and that sophistication of HA translates into higher prices. In Belgium, it is estimated that 800 000 persons are suffering from a hearing loss, even though less than 10% of them use a HA (around 120 000 in 2000-2004, personal communication; D. Ghinet, RIZIV/INAMI). In 2005, 27 064 patients were reimbursed at least 1 HA by Belgian public healthcare payer (RIZIV/INAMI).

In 2005, the public expenses for HA were €19 639 391 (RIZIV/INAMI data). This question is also a matter of health equity. The public healthcare payer currently covers, through a lump sum fee of €484[a], only 25% of the purchasing cost for the most state-of-the-art hearing aid devices. Therefore, the poorest patients have restricted access to these high-tech HA.

Given the above elements, it is important to gain more insight in relative efficacy and pricing of HA sold in Belgium. This report addresses non-implanted hearing aids that qualify for reimbursement by the Belgian public healthcare payer, in an adult population. Most adults wearing or needing HA are more than 55 years old and suffer from presbycusis, hearing loss associated with age, affecting both ears. These patients usually need two behind the ear HA.

---

[a] Tariff applying from January 1st 2008 on, inclusive of ear mould (ear mould reimbursed separately through a 66€ lump sum fee if no hearing aid is eventually chosen by the patient)

Therefore, this report focuses on conventional behind the ear HA. As the RIZIV/INAMI does not question the reimbursement of two HA per patient, the problem of bilateral HA will not be analyzed separately in this report.

The wider economic and regulatory context for these devices will be described for Belgium and for a series of other countries. Clinical effectiveness and cost-effectiveness of hearing aids (HA) will be assessed. We hope that the findings from this report will help to formulate policy recommendations enabling equitable and cost-effective reimbursement practices.

1.2 INTRODUCTION TO HEARING LOSS AND HEARING AIDS

1.2.1 Hearing Loss

1.2.1.1 Aetiology

Hearing loss (HL) is due to disorders affecting the transmission of the acoustic energy to the inner ear (conductive HL), the information's treatment in the cochlea (sensorineural hearing loss; SNHL), or the information's transmission and/or processing in the central auditory pathway (sensorineural and central HL).

Conductive HL changes a person's hearing threshold without distortions; it corresponds to a quantitative loss of audition. Sensorineural cochlear HL is associated not only with a quantitative loss but also with qualitative loss of hearing; the subjects perceive distortions in the characteristics such as frequency, duration, and intensity of sounds. Moreover, the spectral resolution of the cochlea decreases causing the distinction between two sounds to be less accurate. The loudness growth perception of sounds is modified: the soft noises are hardly heard or simply remain unheard, the louder sounds are perceived as too loud. The sounds are perceived as lasting longer than the real sound. The speech intelligibility is affected more and more with the HL degree. At weak HL, the speech intelligibility decreases more in noisy or reverberant environments, or in case of poor articulation. At higher HL, the speech intelligibility falls even in quiet environments: the patient hears but does not discriminate or understand the speech.

In a number of cases, conductive HL can be cured surgically. Bone or air conduction hearing aids (HA) allow for a good compensation of the quantitative auditory loss in the not surgically treatable cases.

The majority of the Sensorineural HL is of cochlear origin. This cannot be surgically cured. Hearing loss must be compensated by hearing aids which amplify the input sounds.

Amplification of sound improves the auditory thresholds but not the auditory distortions. Different processing systems must be added to modify the amplification type for specific intensities or frequencies. Therefore, the HA will always give only a partial correction of the hearing loss.

In moderate to severe HL (averaged hearing loss less than 85 dBHL), sound amplification systems are applied. The conventional amplification HA can be worn in the ear canal or behind the ear. The amplified sound is sent into the external ear canal. New amplification hearing aids are in development now; the partially or completely implantable HA, where the sound amplification occurs on the ossicular chain, claim better sound quality.

In case of profound deafness (averaged hearing loss more than 85 dBHL), the structural and functional disorders of the cochleae are massive. A correct analysis of the sounds, even when amplified, is not possible. The only solution today for this profound HL is a cochlear implant. The acoustic stimuli are coded into electrical information and stimulate directly the acoustic fibres in the cochlea.

As mentioned before, the scope of our report is limited to non-implantable hearing aids.

1.2.1.2 Measures of hearing loss

Hearing loss is measured by laboratory hearing tests, audiograms, also called "objective" tests, and by questionnaires, called "subjective" tests.

Laboratory hearing tests (audiometry)

Even if audiometries are called "objective" tests, they obviously require the subjects' collaboration.

The tonal audiometry measures the intensity thresholds (expressed in decibel; dB) of pure tones, sounds composed of one specific frequency expressed in Hertz (Hz = the measuring unit of frequency in number of cycles per second). The tested frequencies vary between 125 and 8000 Hz. In hearing aids studies, the frequencies < 1500 Hz are sometimes called the "low frequencies and the frequencies > 1500 Hz the "high frequencies".[1]

The normal thresholds are lower than 30 dB HL (dB HL = clinical unit using the hearing thresholds of young normal hearing subjects as reference). The hearing thresholds average (HTA) is frequently used. It corresponds to the average of the intensity thresholds of usually 3 frequencies: 500, 1000, 2000 Hz.

Tonal sounds are also used to measure the sound discomfort levels, corresponding to the maximal acceptable intensity for the subject. A normal subject tolerates intensities of +/- 100-110 dB HL. The intensity differences between the perception thresholds and the discomfort levels correspond to the hearing dynamic range for one specific frequency (dynamic range of audition, hearing dynamic range, or auditory dynamic range are synonyms). The normal hearing dynamic range is higher than 80 dB.

The speech audiometry measures the intelligibility of speech sounds: phonemes, words, or sentences presented at different intensities. The speech reception threshold (SRT) corresponds to the speech intensity giving 50% correct intelligibility. Normally it is lower to 35 dB HL for disyllabic words presented in quiet surroundings. Two other parameters can be recorded during speech audiometry: the maximal speech intelligibility that the subject could reach and the speech recognition score corresponding to the % of intelligibility at an intensity of 40 dB above the speech reception threshold.

The speech audiometry may also be recorded in noise. The speech (=S) stimuli are presented at one intensity, associated to a noise (=N) presented at one specified intensity. The speech to noise ratio (SNR or S/N) corresponds to the difference between the signal and noise intensities. The S/N ratio could be fixed: the proportion of correct intelligibility is recorded and is expressed in percentage of words understood at fixed intensities of speech and noise.[2-4] At a fixed S/N, the difference between 2 test conditions is expressed in % of intelligibility gain. An adaptable S/N ratio is defined as the S/N ratio necessary to achieve 50% correct performance. In the adaptative S/N, the difference between 2 test conditions is expressed in dB gain between the intensities used to reach 50% intelligibility.[5, 6]

An explanation on audiograms can be found in the appendix to this chapter.

Questionnaires

Two kinds of questionnaire are generally used: questionnaires measuring hearing-related health states perceived by the patient and questionnaires measuring generic quality of life.

HEARING-RELATED HEALTH STATES

A great number of self-report questionnaires measuring hearing-related health states perceived by the patient can be found.

The most used questionnaires are:[7-9]

- The "Profile of Hearing Aid Benefit" (PHAB) and its shortened version the "Abbreviated Profile of Hearing Aid Benefit" (APHAB)
- The "Hearing Handicap Inventory for the Elderly" (HHIE) and its shortened version the "Hearing Handicap Inventory for the Elderly – Shortened" (HHIE-S)

- The "Client-Oriented Scale of Improvement" (COSI)
- The "Satisfaction with Amplification in Daily life" (SADL)
- The "Glasgow Hearing Aid Benefit Profile" (GHABP)
- The "Amsterdam inventory for Auditory Disability and Handicap" (AIAD)
- The "International Outcome Inventory for Hearing Aids" (IOI-HA).

A new tool has also been developed recently:[10]

- The "Effectiveness of Auditory Rehabilitation scale" (EAR scale).

These questionnaires are described in the appendix to this chapter.

Other questionnaires measuring hearing aids performance but not hearing aids benefits also exist, i.e. the Profile of Hearing Aid Performance (PHAP), the Hearing Aid Performance Inventory (HAPI) or the Shortened Hearing Aid Performance Inventory (SHAPI).

GENERIC QUALITY OF LIFE

General preference-based measures of health (i.e. utilities) are needed to make comparisons with other health care programmes, since they allow calculating a common outcome for all health care programmes: the Quality-Adjusted Life-Years (QALYs) combining the Health-Related QoL (HRQoL) with the time spent in this.condition.

In a review of studies on the use of preference-based measures of health in economic evaluation, Brazier et al,[11] compared five instruments:

- The "Quality of Well-Being Scale" (QWB)
- The "Rosser's disability/distress scale"
- The Health Utility Index (HUI; mark 1 to 3)
- The EuroQoL 5 dimensions (EQ-5D)
- The 15D

They conclude that utilities assessed by HUI-3 or EQ-5D are preferable, especially because values are obtained using a choices-based technique, which is not the case with QWB, the Rosser's disability/distress scale and 15D.

A new instrument, the Short Form 6D (SF-6D), derived from the Medical Outcomes Study Short Form 36 (SF-36), was developed more recently.[12-14]

Two generic instruments containing questions relevant to hearing and communication have also been developed;[9, 15]

- The "World Health Organization's Disability Assessment Scale II" (WHO-DAS II)
- The "Psychosocial Impact of Assistive Devices Scale (PIADS)".

However no utility scores reflecting patient preferences could be derived from these questionnaires and thus, they do not allow assessing QALYs.

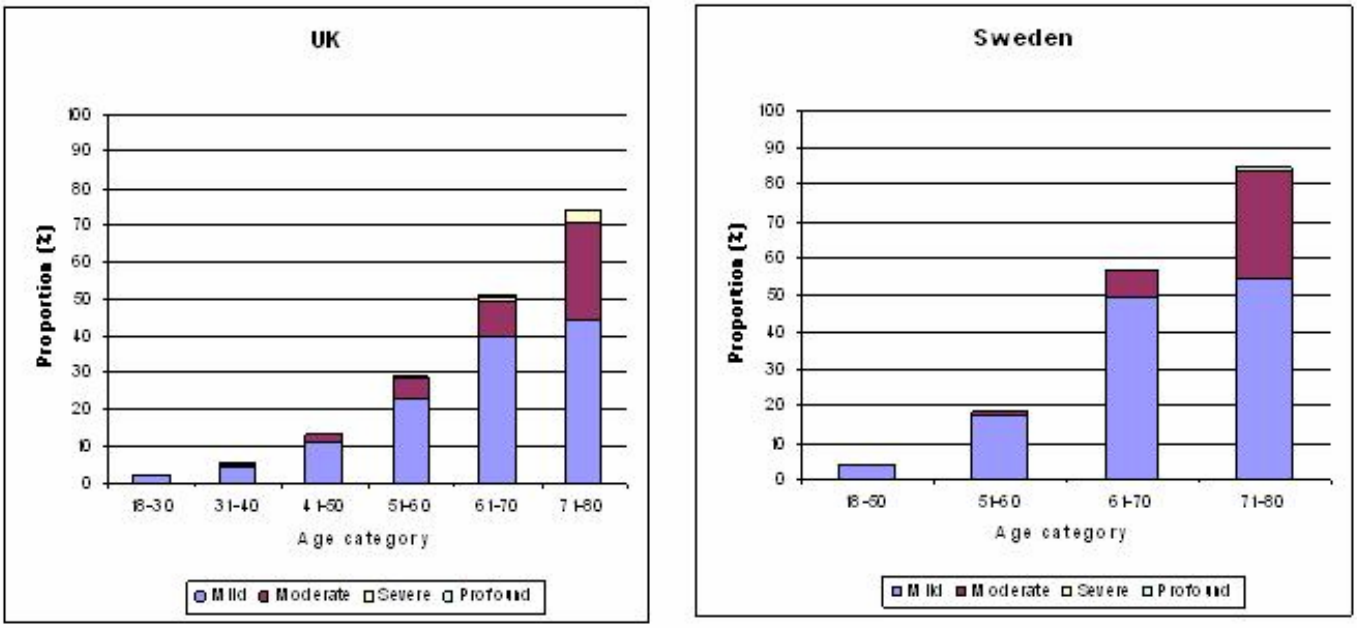
Several studies have compared general preference-based questionnaires to measure quality of life of hearing impaired people.[16, 17] Results showed that HUI-3 was more sensitive than EQ-5D and SF-6D to improvements in utility after the provision of hearing aids. This result is explained by the fact that HUI-3 questionnaire explicitly asks about the capability to communicate, which is not the case with the EQ-5D or SF-6D questionnaires. Because of this sensitivity, the incremental cost-effectiveness ratio (ICER: incremental cost / incremental utility) can be expected to be lower with HUI-3 measures than with EQ-5D or SF-6D measures since there will appear to be more utility gained for the same cost.[16] A more detailed description of these instruments can also be found in the appendix to this chapter.

1.2.1.3 Prevalence of Hearing Loss

In a review published in October 2006 Shield et al.[18] estimate that 22.4% of European adults suffer from hearing loss. This estimate is based on publications from different countries: Denmark, Finland, Italy, Sweden and the UK. Hearing impairment increases with age as reported by Shield (tables 3.11 and 3.12, p22-23). Hearing loss concerns very few 18-30 years olds but 65% to 84% of 71-80 year old persons depending on the studies. When excluding mild hearing loss, this proportion falls to 16.7% to 28.8% of 71-80 year old persons.

Figure 1 displays data from the UK and Sweden. They show the evolution of hearing loss by age and the grade of hearing loss.

Figure 1: Age-related hearing loss.



Source: Shield 2006.[18]

Table 1 and Table 2 show demographic data on Belgian residents aged 60 to 89 years from the Belgian Federal Public Service (FPS) of Economics (National Institute of Statistics, NIS) for 2005 (www.statbel.fgov.be) and the hearing threshold levels published by Engdahl.[19] The frequencies are those used in the calculations justifying HA reimbursement in the Belgian financing system (Hearing threshold average for 1000, 2000, and 4000 Hz).

Table 1: Demographic data and threshold hearing loss for men in Belgium in 2005.

Age categories	Nb Men	% presenting HL of 35 dB	% presenting HL of 40 dB	% presenting HL of 45 dB
60-69 years	474 354	38%	25%	20%
70-79 years	368 254	63%	50%	35%
80-89 years	131 083	80%	75%	65%
Total	973 691	517 120 (53%)	401 028 (41%)	308 964 (32%)

Table 2: Demographic data and threshold hearing loss for women in Belgium in 2005.

Age categories	Nb Women	% presenting HL of 35 dB	% presenting HL of 40 dB	% presenting HL of 45 dB
60-69 years	513 773	18%	10%	-
70-79 years	489 603	40%	30%	20%
80-89 years	251 522	75%	63%	50%
Total	1 254 898	476 962 (38%)	356 717 (28%)	223 682 (18%)

We observe that between the age of 60-89 years, more than 40% of men and 28% of women meet the Belgian criteria[b] for the reimbursement of one HA (HL > 40 dB). The criteria for the reimbursement of bilateral HA (HL > 45dB in the best hear assuming symmetric HL) is observed for one third of men and around 20% of women. Among the population of 60-89 years, 45% suffer from hearing impairment (> 35 dB) but the proportion is higher for men.

Shield reports a mean HL deterioration rate of 1dB over 2 years and around 5 to 6 dB per decade. This rate varies with age: around 9 dB per decade over the age of 55, and about 3 dB per decade under 55 years.[18]

1.2.2 Amplification Hearing Aids

Hearing aids are simple in principle: all consist of tiny microphone(s), amplifier(s), receiver (or speaker), and a battery to power them.[20-23] Microphones take the incoming signal and filter it. Amplifiers take the resulting signal and make it louder. Adjuvant signal processing systems may modify the amplification. The receiver converts the signal back into the acoustical form of the signal that the ear can hear (Figure 2).

An induction coil, if present, can capture the induction current produced by telephones, TV, specific sources in for example theatres, etc. When present the potentiometer controls the amplification of the amplitude (volume control). The microphone-amplifier-speaker complex is combined in a box worn behind the ear (BTE HA) or in the external ear canal (intra ear HA). For the BTE, the sound produced by the speaker is sent in the ear canal through a sound tube and an ear mould.

The acoustic information is processed at different levels of the HA-patient couple. The HA contains one, two or more microphones with fixed or adaptive adjustment to the input signal.

The sound amplification by the HA is called linear when the same amplification is applied to all incoming intensities. When the amplification changes with the input sounds intensity, it is called non-linear: the amplification decreases for loud sounds and increases for soft sounds.

The signal to amplify may be treated analogously or digitally. In the analogue amplifier, the electro-acoustical signal produced by the microphone will be processed and modified by electronic circuits, controlled manually or digitally. In the digital amplifier, the acoustical information is processed completely digitally.[24]

Sometimes, filters are added to the fitting system.

The diameter of the sound tube (placed between the behind the ear box and the ear canal) is chosen in relation to the hearing loss and the spectral response desired. The venting size of the ear mould influences the amplification of the low frequencies.

The use of all these parameters of sound processing may give the user the level of sound they need in different listening conditions. However, it is clear that up to now no hearing aid, even one with all the new sophisticated digital electronics, can amplify speech without amplifying some background noise as well.

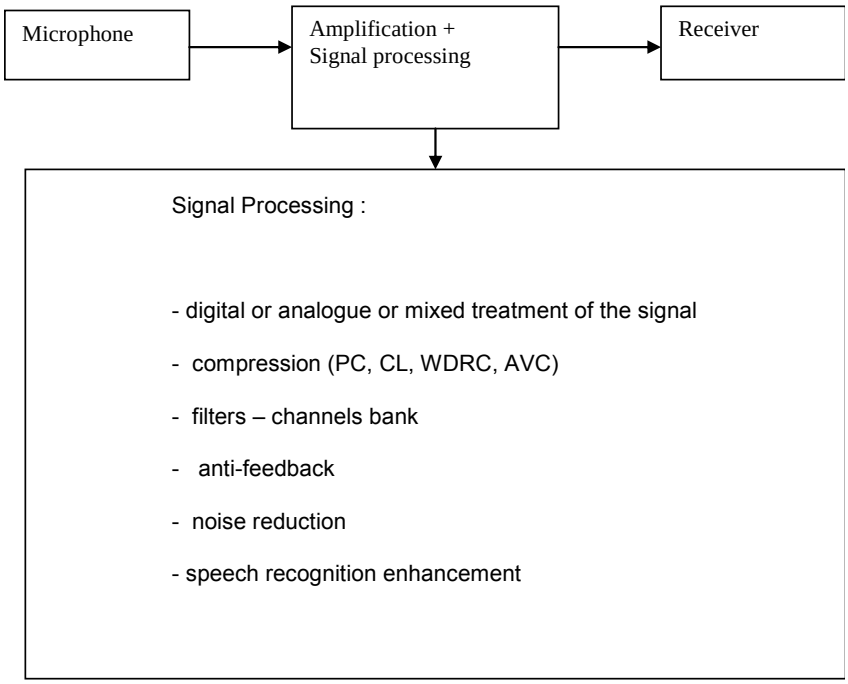
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[b] not taking additional criteria (eg speech index scores) into account.

Hearing aid No HA can completely restore normal hearing. Hearing limitations persist, especially in difficult (noisy and reverberant) environments.

In the next section, we will discuss in more details HA characteristics that are helpful in making a comparison of HA types and prices. The clinical effectiveness of various technological characteristics is discussed with the corresponding literature (chapter 2).

Figure 2: Schematic view of a hearing aid.



PC= Peak Clipping, CL= Compression Limitation, WDRC= Wide Dynamic Range Compression, AVC: automatic volume control

1.2.2.1 Amplifiers types

The amplifiers used in HA are analogue (Class A, B or D) or digital. Analogue class C amplifiers are not used in HA as these give many distortions and are meant to be used as radio-frequency amplifiers in transmitters. These circuits should be combined with a number of other circuits modifying the characteristics of the amplification.

The first conventional hearing aids were electronic. They used analogue Class A technology to provide linear-type amplification.

Advanced Technology Hearing Aid circuits employ a more recent development in amplification electronics known as non-linear or compression amplification. Amplifiers used in these hearing aids are predominantly from the Class D family with the additional benefit of a longer battery life and lower distortion.

Programmable HA rely on a different form of technological innovation as these devices contain a memory module. An external microprocessor accesses the memory to modify the hearing aid's electro acoustical characteristics.

The Digital Amplifier samples the incoming analogue signal from the microphone and digitizes the signal. The Digital Sound Processing circuits are the latest advancement in the hearing aid industry. The amplification, the filtering and the compression characteristics are all digitally controlled. Digital filtering allows much more flexible and precise frequency shaping than analogue filters.

However, the performance of digital HA depends on their sound processing complexity. A digital HA giving a linear amplification, with little filtering, compressing , noise reduction or microphone directionality may be less effective for the patient than an analogue HA producing a non-linear amplification, with adequate compression systems, double microphone and, more filtering parameters.

Digital processing generally scores better in questionnaires then analogue processing.[1, 5, 25, 26] However other authors did not find a difference between the two sound processing methods.[27, 28]

1.2.2.2 Compression systems

The compression systems are digital and act on an analogue or digital signal.

Considering the hearing distortions produced by sensory neural HL, the compression systems are useful to limit:

- The dangerously loud impulse sounds (Peak clipping, PC)
- The gain on loud sounds (output limiting compression = Automatic Gain Control Output, AGCO)
- The weakness of soft sounds amplification and the aggressiveness of loud sounds (Automatic Gain Control of the Input signal, AGCI, allowing a wide dynamic range compression, WDRC).[29, 30]

Peak clipping

Loud peaks cause hearing distortions and discomfort. The peak clipping (PC) cuts the amplitude of these sounds. This cutting is instantaneous but produces some distortions. The PC compression circuit is not expensive and has existed for many years.[31]

Output Limiting Compression

This circuits' type helps to compress the output signal very aggressively once high levels of input are reached. The compression threshold is fixed in the superior value of the subjects' auditory dynamic range (> 80 dB). The compression ratio between the input and output signals is high: 8/1 or more. The gain reduction is not instantaneous: the delay between the input and compression beginning (attack time) varies between 0.05 and 20 msec. The release time of compression may be short (= fast, 5 to 100 msec) or long (= slow, 1000 msec or more).[1, 31, 32] The release time is adaptive in some new devices.

Since the gain of the output signal is automatically controlled these devices are called Automatic Gain Control Output (AGCO). AGCO may be present in analogue and digital amplifiers.

Wide Dynamic Range Compression

It corresponds to an Automatic Gain Control (AGC) working on the input signal (AGCI). For analogue amplifiers, it is called K-amp amplification acting as a Treble Increase at Low Level compressor (TILL). In the digital amplifiers, it is called Wide Dynamic Range Compression (WDRC) or Automatic Volume control system (AVC).[1]

The compression threshold is low (from 20 dB SPL, usually approximately 50 dB SPL; (dB SPL = a physical measure of sounds intensity using a reference of 20 □Pascal; dB = log P/20 □Pascal)).[1] The compression ratios are small (around 2/1). The goal is to amplify only soft sounds while insuring that louder sounds are not too loud. This compression allows a better correspondence between the large dynamic range of input signals and the restricted dynamic range of the patients' hearing. The release time could be short or long. The shorter (or faster) compression release times are sometimes called "syllabic". Some authors limited the name "WDRC" to non-linear amplification produced by fast acting release time compression systems. They call it "Automatic Volume Control" when the non-linear amplification uses slow acting compression systems.[1]

Compared to linear amplification, the WDRC may give higher speech recognition scores.[1, 29] However, linear amplification can sometimes be the better choice.[1, 33]

1.2.2.3 Microphones

Speech understanding in noisy environment is difficult for subjects with HA. The use of a directionally fixed microphone improves the signal to noise ratio of 3 to 9 dB, depending on the signal and the position of the noise sources.[34, 35 36, 37]

A directional microphone is obtained by using a single bi-directional microphone or a dual microphone controlled electrically or digitally. In the fixed directional design, the polar pattern achieved by the microphone(s) characteristics is held constant. In adaptive directionality design, the polar pattern characteristics are under the control of an algorithm adjusted to environmental noises.[38]

The use of more than two microphones gives an increase of 1.5 to 22.5 dB in S/N. An increase of 1 dB S/N may give an increase of 8.5% in speech intelligibility.[38] This improvement is present only in good hearing conditions: non reverberating environment, speech coming from one source (front) and the noise from a source located at 90° to 180°.[35, 38, 39] The improvement decreases to 1.5 dB in more natural conditions, which corresponds to the gain obtained with the hand placed behind the ear.

1.2.2.4 Number of channels

The frequency composition of the input sounds may be analysed and modified through spectral filters or channels. The number of spectral channels varies between HA. The sound information in the different spectral channels may be treated differently in terms of amplification (= gain) and compression.

There is no consensus on the ideal number of channels.[33, 40-43] More channels allow more flexibility in adjusting gain and compression in case of more important hearing loss on specific frequencies. Current digital hearing aids offer up to 32 compression channels. Less than 4 channels seem to be sufficient.[44] One to five channels may be sufficient for moderate hearing loss and three to nine for severe hearing loss. The use of more than 5 channels does not degrade speech recognition as compression ratios are low (the amplification compression or limitation is small).[44] Using other compression ratios, speech discrimination was found to improve from 4 to 8 channels but not over 8 channels.[45] The use of 32 or 64 channels does not give different measured scores.[40]

They are interactions between the number of channels and the compression parameters but these interactions are not always clear.[33]

1.2.2.5 Noise reduction systems

These algorithms are supposed to improve speech intelligibility in noise or at least to increase ease and comfort of listening.

They detect speech on the basis of amplitude fluctuations and rapid modulations of sounds. The noise present between the pertinent speech elements is less amplified in the adequate canal. The temporal contrast between noise and speech is increased allowing an improvement of the speech discrimination in noise.

A small positive effect on speech in noise was shown in studies done on small samples.[45-48] Moreover, a directional microphone alone gives more improvement that noise reduction algorithms alone. Better results are obtained when a directional microphone and the noise reduction algorithms are associated.[48] Some microphone systems allow the reduction of noise produced by wind.

1.2.2.6 Anti Feedback systems

Sometimes HA cause whistling sounds that can be heard by the patient and his entourage. This phenomenon is due to an acoustic loop between the receiver and the microphone, called acoustic Feedback (FB). It is more frequently produced in case of high amplification and incomplete occlusion of the external ear canal (EEC). However, a complete EEC obstruction produces discomfort with autophonia (to hear one's own voice) and the feeling of ear canal obstruction. The discomfort is more marked in case of preservation of low frequency hearing.

The ear mould must be ventilated with an opening called "event or vent", increasing the risk of FB. Various systems were developed to counteract FB. The passive systems reject it by filtering it out. Active systems counter it, using a re-injection in the HA of the tone in opposite phase. They correspond to the adaptive anti FB systems. The best anti FB systems do not decrease the gain of the HA.[49] The uncontrolled feedback is a major factor of limited use or non-use of HA by the subjects.[50] The feedback control is one of the 6 more important HA attributes for the patients.[51] It is therefore important to have an anti-feedback system,[52] or a good ear mould.

1.2.2.7 Recent progress

- Speech recognition systems: they recognize the speech using more specific vocal recognition systems. They are implemented only in the latest and more expensive HA.
- Adjustment to environmental situations: the various systems for hearing improvement should not be used in all conditions. In quiet surroundings, the HA tuning should be different from that in a noisy environment. The presence of different programs allows the patient to change the HA program depending on the situation. In more recently HA, the choice is made automatically by the HA. Moreover, the HA may record the usual sound environments and automatically choose the most indicated adjustment.

1.3 SUMMARY

As many technological devices, the HA technology changes rapidly.

The first HA contained a one-channel analogue linear amplifier, peak clipping (to eliminate brusque and very loud sounds), sometimes compression limitation (compression from a given loud to middle intensity) and filters modifying the amplification of low and high frequencies. The fitting was manual and a volume control allowed the patient to adjust the amplification to various acoustic environments. The single microphone was omnidirectional or directional. The HA power was variable with distortions for high amplifications. These aids had shown their efficacy and effectiveness in improving hearing disorders compared to the non-amplified situation.[38]

The second generation of HA was composed of one or more analogue channels with digitally controlled compression systems, spectral responses and automatic gain controls. Electronically or digitally controlled dual microphones were used in omni or unidirectional modes. The numerical control allowed the use of compression systems activated by very low threshold inputs and the amplification became non-linear. Theoretically, non-linearity could better respond to the reduced dynamic range of audition associated with sensorineural hearing loss. The gain and compression design could be different in each channel, in case of multi-channel HA. Noise reduction's algorithms were available, improving speech intelligibility in noise. The anti-feedback treatments could be used. The use of audio input or magnetic coil was possible.

Various publications showed that programmable technology was related to higher satisfaction levels compared to non programmable technology.[53] However, because of methodological bias, the results of those studies are questionable. Since 2003, no clear evidence has shown that digitally controlled analogue HA was superior to manually controlled HA.[54] However, the manufactures have invested more in those types of HA and stopped the development of the older ones.

The current third generation of HA is fully digital. Between the sound input and the receiver all the signal treatments are digitally. The channel numbers tends to increase up to 32 channels. The compression parameters are more complex and flexible: compression ratio, compression activation level (threshold or 'knee point'). The attack and release time, and the compression linearity can be modified. Gain and compression parameters can be changed independently in different channels. The microphones functioning can be adaptive, dynamic and not fixed. The anti-feedback systems do not decrease the total amplification. More complex noise reduction and speech recognition algorithms tend to improve the speech intelligibility in noise.

The digitalisation is supposed to allow more standardization of the fittings which should decrease the audioprothesist effect while in fact, the audioprothesist effect remains. Indeed, a limited knowledge of the fitting algorithms may produce the adverse effect, i.e. bad functional results due to non adapted fitting parameters.

Until now, there is no evidence that the full digital HA is superior to the simpler analogue HA. Nevertheless, the manufacturers are now exclusively developing digital HA and the analogue HA are no more developed and will probably disappear.

Key points

- **This report addresses non-implanted hearing aids that qualify for reimbursement by the Belgian public healthcare payer, in an adult population.**
- **The wider economic and regulatory context for these devices will be described for Belgium and for a series of other countries. Clinical effectiveness and cost-effectiveness of hearing aids (HA) will be assessed.**
- **The findings from this report will help to formulate policy recommendations enabling equitable and cost-effective reimbursement practices.**
- **Hearing loss is due to disorders in the transmission of the acoustic energy to the inner ear (conductive HL), in the information treatment in the cochlea (sensorineural HL), or in the information transmission and/or processing in the central auditory pathway (sensorineural and central HL).**
- **We observe that between the age of 60-89 years, more than 40% of men and 28% of women meet the Belgian criteria for the reimbursement of at least one hearing aid.**
- **Hearing aids are simple in principle: they all consist of tiny microphone(s), amplifier(s), receiver (or speaker), and a battery to power them.**
- **HA manufacturing has evolved from simple analogue devices to complex full digital devices.**
- **Analogue devices are no longer developed by the industry and as such they are expected to disappear from the market.**
- **At present there is no evidence that the full digital HA are superior to simpler analogue HA.**

2 CLINICAL EFFICACY AND EFFECTIVENESS OF VARIOUS TECHNICAL CHARACTERISTICS OF HEARING AIDS

2.1 INTRODUCTION

The absolute number of elderly subjects, and their relative proportion is increasing in western societies. Therefore, the proportion of hearing impaired (HI) people needing hearing aids (HA) will continue to increase. At the same time the technological complexity of the hearing aids is growing, with usually an associated increase of their cost (see chapter 4). This evolution leads to financial pressure on both patients and the national health insurance.

Health care decisions should preferably be evidence-based. For that purpose, good quality evidence on efficacy and cost-effectiveness of the various types of HAs should be available. An important number of trials have been conducted on hearing aids and the resulting evidence has been synthesized by several reviewers.[38, 55-59]. However, the vast majority of these authors emphasized that the small number of well-conducted studies hampered firm conclusions about the benefits of specific technical aspects of HAs.

The aim of this chapter is to update the evidence-base on HAs through a systematic literature review of the clinical effectiveness of HAs in HI adults, based on the best available evidence, i.e. well-conducted randomized controlled trials (RCT). Evidence on cost-effectiveness is reviewed in chapter 3.

2.2 METHODS

2.2.1 Literature search strategy

We conducted an extensive search followed by a more focused search through exclusion in two stages. The search used the key words: "hearing aid" AND ("efficacy" OR "effectiveness"). Wildcards were used to allow for other combinations with effic* or effect*). The search was limited to adult populations and to studies published in the years 1995-2007 because of the rapid technological evolution of HA. The searches were undertaken in February 2007 in 9 electronic databases (see appendix to this chapter for details). References of selected studies were also hand searched to retrieve additional publications. Details about the search strategy can be found in the appendix to this chapter.

In total, 693 different articles were retained after this search (see Figure 41 in appendix to this chapter.

2.2.2 Selection criteria and method

In a first step, clinical efficacy/effectiveness studies were selected for inclusion if they reported on the comparison of 2 or more hearing aid technologies in adults.

We screened titles and abstracts and excluded articles with main focus on:

- General information on the hearing aids
- Description of technical aspects of a specific hearing aid
- Focus on Hypoacusis and associated pathologies, otosclerosis, tinnitus, with no information on HA treatment
- Unconventional hearing aids (such as Bone Anchored Hearing Aid or BAHA, cochlear implants, Retro-X which is a partially implantable hearing aid, etc…)
- Hearing aids for children
- Hearing aids and radiological examinations
- Description of study method without comparison of HA or fitting parameters
- Case reports

- Analyses of country outside Europe and USA
- Factors to be taken into account in the use of HA but without comparison of HA
- Comparison with normo-hearing patients
- Specific comparison of monaural and binaural HA
- Neurological examinations linked to hypoacusis

This selection was made by 2 independent researchers (MD and DR) and their results were compared to obtain a common set of articles. Finally, 100 potential articles were selected at this stage, including 9 that were found through hand-searching (see Figure 41 in appendix to this chapter).

In a second step, the papers were included if they met specific criteria:

- Either RCT or randomized cross over study designs
- Including at least 30 patients in total. We chose the cut-off of 30 patients for statistical reasons. Indeed, with a sample size lower than 30, the power to detect a treatment effect as important as a half SD is lower than 80% in a cross-over trial

As a result of this second stage, 14 papers, reporting on 8 different studies, were retained.

For validation purposes, we then applied a more specific search strategy in OVID-Medline (hearing aids/ AND (randomized controlled trial.pt. OR randomized controlled trial.mp)[c] with limits 1995-2007) and in Embase (('hearing aids'/exp) AND ([controlled clinical trial]/lim OR [randomized controlled trial]/lim) AND [humans]/lim AND [1995-2007]/py). Applying the same selection criteria, one additional study was found, not originally retained because the randomized design was not reported in the abstract.

So in total, 15 papers reporting on 9 studies were included in this review. The flow chart of the search strategy can be seen in the appendix to this chapter (see Figure 41 in appendix to this chapter.

2.2.3 Data Extraction and quality assessment strategies

Data were extracted using a structured data extraction form from the Dutch Cochrane Centre (www.cochrane.nl).[60] The outcome description was adapted to the specific needs of our HA study because the outcomes of improving hearing loss are not measured by only one indicator.

Data extraction was done independently by two reviewers (CB and ND) and then compared. The extracted data were:

- The study's aim and design
- The studied populations: number included, age ranges, past experience of HA or novices
- The studied HA: analogue/digital, linear/non-linear, compression circuits, technological complexity, binaural or monaural fitting
- The laboratory-based tests for efficacy measurements: tonal audiometry, speech +/- noise tests, spectral responses of the hearing aids
- The subjective tests for effectiveness measurements: questionnaires on hearing quality, on quality of life or disability, on HA preference, diary
- The results expressed as efficacy and effectiveness

[c] Sensitivity=93%; specificity=97% http://hiru.mcmaster.ca/hedges/#Therapy

The quality assessment was also done independently by two reviewers (CB - ND) and then compared. This assessment was done using the criteria of Jadad (1996) used by Taylor.[59] This tool offers a weighted score of the study quality:

- Adequate description of randomization
- Blinding of at least the outcome assessor
- Description of the withdrawals and follow up of 80% achieved
- Study outcomes analysed by intention to treat
- Formal pre study power calculation performed
- Use of validated outcome measures

Each item received a score of 1 point if the answer was "yes" or 0 point if the answer was "no". A global "Jadad score" was determined, with a maximal value of 6.

2.3 RESULTS

2.3.1 Included studies

Fifteen papers were included and Table 3 shows the main characteristics of the 9 studies. Seven articles concerned the same trial of 360 subjects [2, 31, 61-65] each describing a specific aspect of the trial: the design, the methodology, the HA technology, the laboratory-related outcome measures, the questionnaires. As the first publication from this study was too synthetic,[2] all articles dealing with this trial were kept for the review in order to have a complete description of the trial. Three publications were done by the same team (department of Audiology, Hospital Bispebjerg, Copenhagen-Denmark) reporting 3 different trials.[3, 4, 66]

Table 3: Characteristics of the published trials (publication date and "Jadad score") and of the studied populations (study time, number of included subjects and drop outs, ages intervals , experience status, mono or binaural fittings, HL types).

Articles	Year of Publication	Jadad score	Year of study	N	Drop out	Age (years)	HA experienced=1 ; naive=3; 2= the 2	HA mono=1, 2= the 2, binaur=3	SNHL exclusiv ely	mild to severe HL	Design
Biering-Sorensen [3]	1995	3	1992	42	10 (24%)	60-80	1	1	No	Yes	Cross-over, single blind
Gatehouse [67]	2006	5	?	61	11 (18%)	54-82	1	1	No	Yes ??	Cross-over, double blind
Larson [2]	2000	4	1996	360	29 (8%)	29-91	2	3	Yes	Yes	Cross-over, double blind
Nilsson [4]	1997	3	1996	54	9 (17%)	60-80	1	2	Yes	Yes	Cross-over, double blind
Parving [66]	1997	2	1996	44	10 (23%)	22-84	1	2	Yes	Yes	Cross-over double blind
Ricketts [32]	2001	1	?	47	?	36-94	2	3	Yes	Yes	Cross-over no blinded
Van Toor [6]	2002	3	?	38	?	34-84	2	3	Yes	Yes	Cross over, unspecified blinding
Wood [5]	2004	3	2001	100	3 (3%)	19-80	3	1	Yes	Yes	Cross-over, single blind
Yueh [25]	2001	3	1998	64	4 (6%)	50-86	3	3	Yes	Yes	RCT not blinded

2.3.2 Heterogeneity of the studies

The trials included presented a great heterogeneity.

2.3.2.1 Design and reporting

All the included trials were randomized, but blinding of patients and assessors were not always realised or properly described. As can been seen in Table 3, the most common design was a cross-over trial where patients tried, in a random sequence, two or more hearing aids technologies. Only half of such studies were double-blind (4/8). The trials were generally of limited quality, the drop out rates were generally not clearly reported, the numbers in the text, graphs or tables did not always match, and the outcomes were rarely analyzed by intention to treat. A summary of each article can be found in the appendix to this chapter.

2.3.2.2 Subjects

There are variations in the number of subjects, in the age ranges, in previous HA experience (naive to HA, experienced or mixed), the fittings' types (mono or binaural) and the type of hearing loss. The majority of the trials included experienced and naive subjects with mild to severe sensorineural hearing loss, except in the Biering-Sorensen and Gatehouse studies where some patients presented conductive hearing loss.

2.3.2.3 Hearing aids used

Table 4 shows an overview of the hearing aids used in the selected trials. Different types of HA were used with different research objectives: comparison between linear and non-linear HA,[2-5, 66] comparison of 3 different compression circuits (PC, CL, WDRC),[2] comparison between various compression time constants,[6, 32, 67] comparison between digital and analogue HA,[5] comparison between programmable and non programmable analogue HA,[25] comparison between emphasis of high frequencies or not,[6] and comparison of omnidirectional and directional microphones.[32] Gatehouse, Larson, Parving and Van Toor compared various fitting parameters rather than comparing different HAs.

The brand and characteristics of HA were not frequently described. The analogue HA (possibly digitally programmed) were more frequently used than the digital HA (Table 4). As described below, the linear versus non-linear amplification was the focus of several studies. However, it should be noted that the tested hearing aids often differed by several other technical characteristics apart from the parameter under investigation: the number of channels (1, 2 or more), the presence of a directional or omnidirectional microphone, the presence of one or different compression circuits (Peak Clipping [PC], Compression limiter [CL], Wide Dynamic Range Compression [WDRC]), the compression parameters, the noise reduction algorithm (for the most recent ones), the presence of a volume control, or the number of available memories.

Table 4: Hearing Aids types in the selected trials.

	Analogue HA		Digital HA	
	Linear	Non-linear	Linear	Non-linear
Biering [3]	E35F	Multifocus (Oticon)		
Gatehouse [67]			Jump-1 (Oticon)	Jump-1 (Oticon)
Larson [2]		Dyna P2 Phonak		
Nilsson [4]	Rexton Setinette	Compressive amplification (K-HA)		
Parving [66]		ReSound		
Ricketts [32]	Not specified	Not specified	Not specified	Not specified
Van Toor [6]				Philips Spaceline D71-40 BTE
Wood [5]	NHS BE 103 NHS BE 38			Danalogic Danavox Siemens Prisma Oticon digifocus
Yueh [25]	Not specified	Not specified		

2.3.2.4 *Outcome measurements*

The HA efficacy was measured with objective hearing tests. The HA's effectiveness was estimated by benefits in everyday life, as measured by questionnaires on quality of life, communication abilities, adherence data, preference, and willingness-to-pay.

Efficacy

Various tests were used (see appendix to this chapter). There was important heterogeneity in the speech tests used in the studies, particularly in noise. The speech materials, the intensities of sound presentation, the Signal/Noise ratios (S/N or SNR) and the presentation designs were very different in the studies. The studied speech parameters are the speech recognition threshold, the maximal recognition score and the word recognition score. All these tests were realized in different conditions in the various selected trials.

Effectiveness

In some studies, the questionnaires used were specific to the study with unknown external validity. Other studies used validated questionnaires to measure quality of life or communication abilities. Table 5 gives an overview of the questionnaires used in the selected studies.

The "Hearing-related quality of life" questionnaires used in the selected publications included assessment of physical, emotional and social functions:

- Hearing Handicap Inventory for the elderly (HHIE): hearing related quality of life scale with two subscales (emotional and social impact of hearing loss)
- The Glasgow Health Status Inventory (GHSI):[68] current state of quality of life, total score and three subscores (general, social and physical)
- Visual-analogue bipolar scale (VAS) for one question concerning the distress provoked by the state of health and disability, including Hearing Loss; a 100 mm line from no to extreme distress.

Other questionnaires studied the self-rated communication abilities:

- Abbreviated Profile of Hearing Aid Benefit (APHAB): four subscales (ease of communication, background noise, reverberation, aversion to amplified sounds. It is designed to be self-administrated but since there are some semantic difficulties, it seems more simple to administrate it during an interview[5]
- Glasgow Hearing Aid Benefit Profile (GHABP) assess hearing disability, handicap, hearing aid use, benefit and satisfaction
- Satisfaction with Amplification in Daily Life (SADL):[69] four subscales: positive effect, negative features, service and cost, personal image
- Hearing Aid Performance Questionnaire (HAPQ): specific for differentiating linear and non-linear fitting. Three subscales: speech variations, environmental sound variations and environment with intense sounds[67]
- Auditory Lifestyle and Demand Questionnaire (ALDQ):[1] specific for appreciating the auditory ecology (the acoustic expositions of the subject in real life, see below). It uses a three-point scale for 24 examples of listening circumstances. A first scale assesses their frequency of occurrence and the second weights their importance
- Direct visual analogue rating scale (DVARS): rates three factors: speech clarity, listening comfort, overall rating of the performance of each hearing aid fitting[67]
- Personal questionnaires[66]

Other questionnaires assessed the willingness-to-pay (how much the patient values a treatment or health state) or the preferences of the patient for the tried HA.

Table 5: Questionnaires used in the selected studies.

	Structured interviews	HHIE-S	APHAB	GHABP	PHAP/ PHAB	GHSI + VAS	SADL + HAPQ+ALDQ
Biering [3]	*						
Gatehouse [67]							*
Larson [2]					*		
Nilsson [4]	*						
Parving [66]	*						
Van Toor [6]			*				
Wood [5]			*	*		*	
Yueh [25]		*	*				

Gatehouse et al.[67] built indicators using subjective and objective tests. The subjective tests were integrated in three factors, called "benefit factors": "listening comfort", "satisfaction with the HA" and "reported intelligibility". The numerous objective tests used were integrated in one benefit factor: "speech tests".

2.3.3 Outcomes

The important heterogeneity of, study design and reporting, subjects, specific hearing aids used, and outcomes measurement among studies made any meta-analysis quite irrelevant. Therefore, results are organized according to the main technical characteristics tested in the trials: non-linearity of the signal, compression circuits, analogue versus digital devices and directional versus omnidirectional microphones. In addition to the technical characteristics of HA, also the HA benefit was studied.

2.3.3.1 Hearing Aids benefit

Yueh[25] and Larson[2] described a benefit in the aided conditions compared to the unaided ones for all the measures, except for sound aversion (= aggressiveness) and perception in noisy environment. The HA benefit increased with hearing loss importance. It decreased in noisy compared to quiet environments.[2]

This decrease in performance is more marked for the less deaf group. In other words, the HA improve the hearing loss in quiet environment but are less efficient for hearing in noise, especially in the less hearing impaired subjects.

2.3.3.2 Effect of linearity

As described before (1.2.2), the sound amplification is called linear if it stays stable and fixed during a large part of the hearing dynamic range: the incoming sounds always receive the same increase in intensity (gain), before being sent into the patients' ear. It is called non-linear when a compression decreases the amount of sounds amplification starting already at low sound level inputs (= compression threshold or 'knee point'), with more or less strength (compression ratio), and more or less quickly (attack and release time of the compression).

The comparison between the linear and non-linear amplifications showed various results in the selected publications. Some authors showed no difference between the two fittings (Nilson,[4] and Ricketts[32]) Others showed few differences in some conditions, more frequently in favour of the non-linear amplification (Biering,[3] Parving,[66] and Larson [2]). Only one author demonstrated a large difference with better results with the non-linear treatment (Gatehouse [67]). Table 6 shows the results of the comparisons that were observed in the overall populations of the different studies.

Table 6: Comparison between the linear and non-linear amplifications in speech tests, questionnaires and patients' preference for the overall populations.

Authors	Speech Tests	Questionnaires	Preference
Biering [3]	Non-linear = linear	Non-linear > linear	Non-linear > linear
Gatehouse [67]	Non-linear > linear	Non-linear > linear	
Larson [2]	Non-linear > linear	Non-linear > linear	Non-linear < linear
Nilsson [4]	Non-linear = linear	Non-linear = linear	Non-linear = linear
Parving [66]	Non-linear = linear	Non-linear > linear	Non-linear > linear
Ricketts [32]	Non-linear = linear		

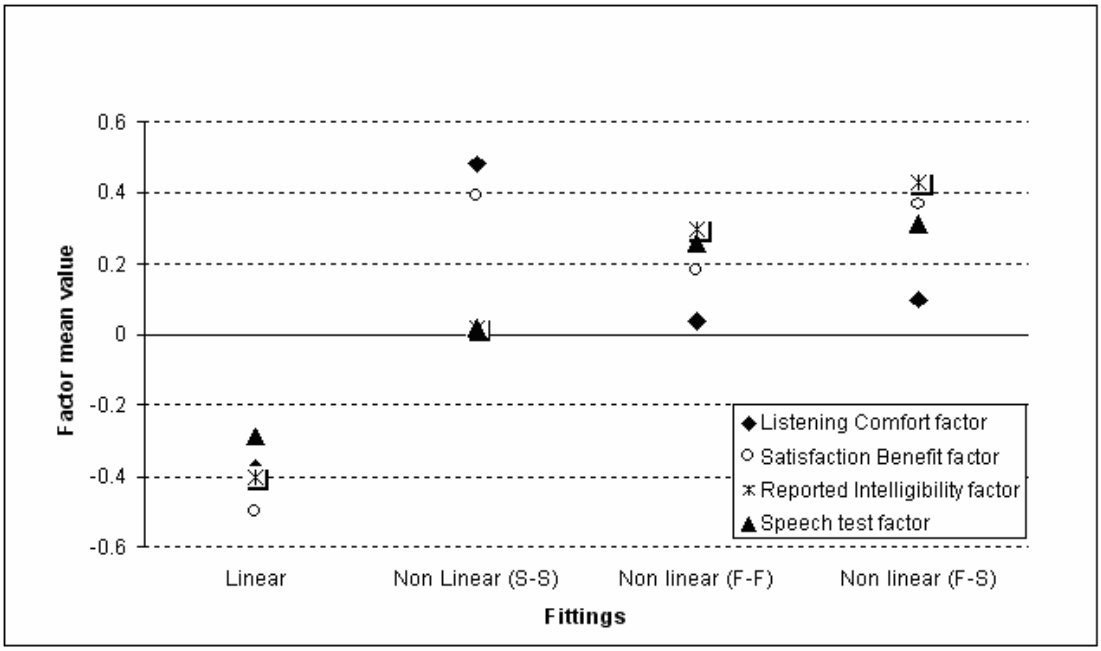
When present, the differences between the two fittings were very small, except in the Gatehouse study.[67]. Differences were more frequently demonstrated with the questionnaires than with the hearing tests; in contrast with the absence of demonstrated effect on audiometric measurements, patients reported a better hearing gain in their daily life with the non linear signal and tended to prefer it to linear HA: 75% (24/32) of patients did so in the study by Biering ($p<0.05$),[3] and 72% (23/32) in the study by Parving.[66]

Studies using a limited number of subjective tests failed to show a significant difference(Nilson,[4] Paving,[66] and Biering [3]).

Gatehouse showed a clear advantage of the non-linear HA for the 4 benefit factors analysed: listening comfort, satisfaction, reported intelligibility and speech test benefit. But, he used a large range of subjective hearing tests pooled together that may favour the observation of a clear benefit of non-linear over linear amplification.[67]

Nevertheless, it must be kept in mind that the results observed for the non-linear HA depend on the compression parameters used and the outcomes measured (Figure 3).

Figure 3: Comparison of linear and non-linear fittings in study by Gatehouse.[67]



In the non-linear fitting, effect of changes in the compression's release times in the 2 HA's spectral channels: < 1500 Hz and > 1500 Hz . Slow= 640 msec, Fast= 40 msec. Example: Fast- fast = 40 msec in the channels < 1500 Hz and > 1500. An effect is present if the benefit factor changes ≥ 0,33.

Larson[2] also showed that the benefit of non-linearity is related to the outcome measures. Table 7 shows the effect of compression types on speech tests and speech perception rating, in quiet and noise for the overall population. The results were also related to the hearing loss importance. Only small differences were observed between the different circuits of compression (peak clipping, compression limits, wide dynamic range).

Table 7: Benefit of the compression circuits in the different audibility conditions for the overall populations.[2]

Speech recognition test		p
Words recognition at 62 dB in quiet	WDRC > PC-CL	0.017
Recognition of sentences at 62 dB in noise	WDRC< PC-CL	0.017
Loudness subjective rating		
Recognition of sentences at 52 dB in quiet	WDRC > PC-CL	< 0.001
Recognition of sentences at 52 dB in noise	WDRC > PC-CL	< 0.001
Recognition of sentences at 74dB in quiet	WDRC > PC-CL	< 0.001
Recognition of sentences at 74 dB in noise	WDRC > PC-CL	< 0.001
Noise interference (subjective rating)		
Recognition of sentences at 62 dB in noise	PC > WDRC-CL	< 0.01
Overall liking (subjective rating)		
Recognition of sentences at 74dB in quiet	WDRC > PC-CL	< 0.001

For speech recognition tests, only very small differences were observed between the different circuits in some conditions. The WDRC gave better results in quiet and less good results in noise for all patients together. However, it was more efficient in noise for the deafest patients and less efficient in noise for the less deaf patients.

For the subjective rating of speech, the WDRC circuit was judged louder at 52 dB and softer at 74 dB than the other circuits.[64] This means that, with more amplification of soft sounds and less amplification of loud sounds. WDRC offers a better adequacy of the amplification to real-life conditions.

The overall population found subjectively PC amplification in noisy conditions less noisy and, therefore, better.

The overall liking was also higher for WDRC and CL than for PC amplification. It was mentioned that PC amplification gave more problems of aversion and distorsion ($p<0.001$).

In questionnaires dealing with preferences, the first choice was most frequently the CL (41.6% of patients), followed by the WDRC (29.8% of patients) and then the PC circuit (28.6% of patients) ($p = 0.002$).

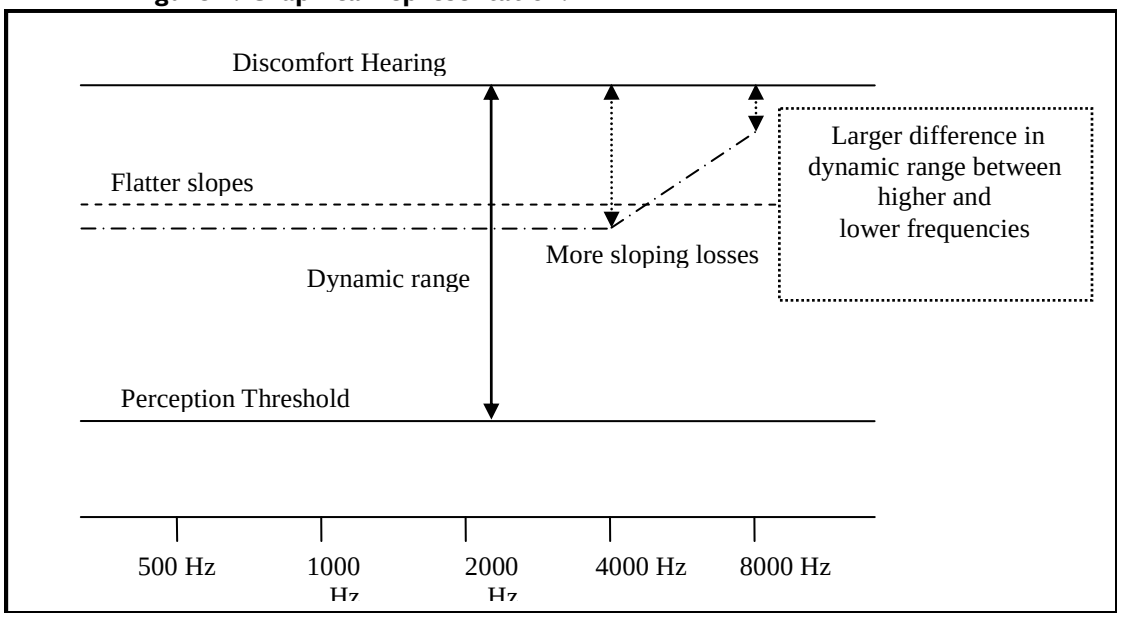
The selected studies tended to, or clearly showed a benefit of the non-linearity on the overall populations.
However a significant number of patients were better served by a linear HA. Gatehouse[67] showed that the linear fitting gave greater benefits in case of:

- equivalent HL at all frequencies (= flatter slopes in audiological measurements)
- greater difference between perception threshold and discomfort hearing threshold (= greater dynamic range)
- smaller difference between the HL level and the discomfort hearing threshold at higher and lower frequencies (= smaller differences in dynamic range between higher and lower frequencies)

See Figure 4 for a graphical representation of these HL characteristics.

Greater benefits from linear HA were also observed in case of a less varied lifestyle and acoustic environment.

Figure 4: Graphical representation.



The opposite features were observed for the non-linear HA's where better benefits were associated with: greater HL at high frequencies (= more sloping losses), smaller difference between perception threshold and discomfort hearing threshold (= more reduced dynamic ranges), greater difference between the HL level and the discomfort hearing threshold at higher and lower frequencies
(= greater differences in dynamic range between higher and lower frequencies), and with a more varied lifestyle and acoustic environments.

Because of the importance of lifestyle, but also because of different hearing demands by different patients, Gatehouse [67] developed the concept of a subjects' "candidacy": characteristics that may determine the benefit obtained with different fittings. The outcomes are related not only to the measured audiometric data, but also to the resistance of the subjects to modifications of the frequency spectrum, of the duration, and of added noise (masking effect). The characteristics are also related to the cognitive capacity and to what he called the "auditory ecology" of the subjects: the range, types and importance of listening circumstances which individual listeners encounter, using self-reported (questionnaires) and acoustical measures (dosimeters data).

The subject should be a candidate for a linear fitting in case of flatter audiometry (same hearing loss on high and low frequencies), greater dynamic range of audition, and less varied lifestyles and acoustic environments. Conversely, he should be a candidate for non-linear amplification in case of more important hearing loss (more on the high frequencies), with limited hearing dynamic range, larger variation in lifestyle associated with more acoustic environment changes.

Larger hearing demands are associated with more benefit from the non-linear amplification. These conditions are more frequently encountered in younger than older adults.[67]

The contradictory results of the various publications may be explained, at least partially, by differences in population age, outcome measures, patients' hearing loss types and lifestyles. They may also be influenced by the used compression parameters.

2.3.3.3 Parameters of compression

Three authors studied the effect of various release times of compression on the hearing aids outcomes: Ricketts[32] did not show any effect, Van Toor[6] found some effects in some conditions, and Gatehouse[67] described a clear effect depending on the subjects characteristics and acoustic environmental data (Table 8).

Table 8: Effects of compression release times changes on outcomes.

	Gatehouse	Ricketts	Van Toor
Compression release-times	- 2 spectral channels: < or > 1500 Hz - Fast= 40 msec Slow= 640 msec Fast-Fast: 2 channels at 40 msec Slow-Slow: 2 channels at 640 msec Fast-Slow: channel < 1500 Hz at 40 msec channel > 1500 Hz at 640 msec	- 93 to 270 msec	- 2 spectral channels with different release times. - Fast: channel 1 at 2 to 64 msec channel 2 at 2 to 16 msec - Normal: 16 to 512 msec and 2 to 64 msec - Slow: 64 to 2048 msec, 32 to 1024 msec
Results	- Slow-Slow better for listening comfort and satisfaction benefit factors - Fast-Fast better for reported intelligibility and speech tests	No difference	- No overall preferences - Fast: better in noise

In the overall population, Gatehouse showed that the effects of release times depended on the outcome measures: if the speech tests and the intelligibility factors were better with fast acting compressions, the satisfaction factors and the listening abilities were higher with the slow acting. Van Toor showed no overall preference of compression algorithms in his overall population.

However, patients using fast compression mode obtained larger improvement in speech tests, as also described by Gatehouse. Large inter-subject differences where present in the two studies, suggesting that each individual hearing aid user needs different time constants for optimal performance.

To better understand what should be the best compression release times Gatehouse analyzed the individual scores obtained by the subjects. He showed that the "slow-slow"" fitting can be regarded as a safe option as it is often associated with good scores for listening comfort, and rarely disastrous scores for the other parameters. The other fittings ("Fast-Fast" or "Fast-Slow") often gave either optimal or poorer intelligibility to different individual listeners.

The diversity of results was analyzed tacking into account the patient's profile, called the "candidacy" effects.

Gatehouse showed a greater benefit from the slow acting release of compression if the subjects are exposed to larger variations between sections of listening experiences, that means with large periods of stable listening conditions (for instance, in older subjects). The fast acting release of compression gave better results in subjects with larger cognitive capacity and with higher resistance to spectral or temporal cues modifications in speech.

2.3.3.4 Effect of analogue or digital HA

Wood[5] compared three types of multi-channel, multi compression circuits, digital HA to two single-channel analogue HA. The digital HA scored better in speech recognition scores, satisfaction score (GHABP), in aversion (APHAB) and were more frequently preferred. There was a significant difference in favour of the digital hearing aid for the satisfaction scale of the GHABP ($p < 0.05$). The digital aid gave less aversion responses than the NHS HA ($p<0.001$).

Yueh[25] compared two analogue HA, one non-programmable non directional with compression limiter (CL) and one programmable with switchable directional microphone, three memories (compression parameters not communicated).

He reported better scores for the more complex HA at the APHAB, HHIE, daily use duration of the HA (8.8 versus 6.9 hours) and substantial differences in willingness to pay ($2240 compared to $800). He showed also that HA wearers gave higher scores than not aided subjects.

Ricketts[32] showed no difference between the analogue or digital tested hearing aids.

These studies indicate that more complex hearing aids could be associated with more benefits for the patients.

2.3.3.5 Directional versus omnidirectional hearing aids

Ricketts showed that a directional microphone gave better speech recognition than an omnidirectional microphone in noisy environments.[32] The improvement in average speech recognition scores ranged from 13% to 23% over those measured in omnidirectional mode, depending on the particular hearing aid model.

2.4 DISCUSSION

Despite the large quantity of publications on hearing aids, we found in this systematic review only nine randomized studies published between 1995 and 2007.

This confirms the previously described limited number and poor quality of large trial publications on hearing aids effectiveness (Taylor 2001,[59] Bergeron 2003,[38] and NICE cited by Gatehouse[67]). The majority of the trials could also be considered as relatively old taking into account the speed of technological changes (5 to 10 years old).

There might be different reasons for this limited number of randomized studies. The main reason is probably that providing evidence of clinical benefit is not mandatory to market a new hearing aid. This does not encourage scientific studies on large number of patients.[67] Generating high quality evidence is also made difficult by the following elements:

- Blinding is very difficult if the same external hearing aids are not used. Nevertheless, blinding is important to avoid the influence of the patients' a priori beliefs. Patients' beliefs and expectations could influence the results, for example if they expect the digital HA to be better than the analogue HA.[58, 59, 70] They may also expect new technology to be better and give it a higher score.[58, 59, 70]
- The technological characteristics of the evaluated hearing aids may vary on more than one parameter, making conclusions about the benefit of one specific item difficult.
- The speech tests and questionnaires used were not always standardized. Moreover, these tests are sometimes difficult to perform by older patients because of their duration.

All these limitations could explain the paucity of high quality publications and the fact that trials were conducted mainly in organized settings such as a military medical structure,[2, 31] or in countries with a national centralized medical care for HA: Denmark (Nilsson,[4] Parving,[66] Biering,[3]), the Netherlands (van Toor[6]), and UK (Wood,[5] Gatehouse[67]).

Despite those limitations, we found some important information about the benefits of specific technological aspects of hearing aids in this literature review.

2.4.1 Discrepancies between objective and subjective tests

There was often a discrepancy between results from audiometric tests and from questionnaires. The questionnaires reported more often significant changes between two HA, as shown in the studies of Nilsson, Parving and Gatehouse.[4, 66, 67] Indeed, hearing is a multidimensional construct depending on internal (beliefs) and external factors acting upon subjects: hearing levels, perceived hearing difficulties, personal image, social relations, reaction of relatives and professionals, HA reliability and comfort etc… Questionnaires perform better to integrate the internal and external factors.[9] Therefore, the overall appreciation of a HA is not only related to its physical characteristics but also to the perceived hearing difficulty without HA, the perceived quality of sound through the HA, its usefulness in multiple listening environments and the fit comfort.[53, 71, 72]

2.4.2 Hearing aids benefit

The selected studies showed a benefit of hearing aids when the aided and unaided conditions were compared. The systematic reviews of Chisolm on health-related quality of life and hearing aids and the one by the Swedish council of technology assessment (SBU) reached the same conclusions.[55, 73] However, Larson reported that the hearing aids used in that study (analogue HA) helped the more impaired subjects better in quiet environments than in noise.[2] For the aversion score, the subjects were even worsened in the aided condition. The less HI subjects were more negatively influenced by noise in the aided condition compared to the unaided ones. Similar observations were made by other authors.[9, 74, 75]

2.4.3 Linearity

Gatehouse demonstrated a clear benefit of the non-linear over the linear fitting on the overall studied population.[67] This observation was probably partly due to the use of a large range of subjective and objective data, pooled together before the statistical analysis. The other authors reported less convincing effects and this has also been confirmed by other authors that were not selected for this review.[58, 76] The non-linear amplification is useful for many hearing impaired subjects, especially if they are more hearing impaired, particularly in high frequencies, and with smaller difference between the hearing level and the discomfort hearing threshold at higher and lower frequencies. But a linear amplification is sufficient and gives better hearing results in subjects with less hearing impairment, less changes in their acoustic environment, or less hearing demands.

The HA choice should take into account not only the hearing thresholds but also the lifestyle, and the hearing demands of the subject: a very old patient living in a quiet environment, with small acoustic environmental changes and with limited hearing demands, may be helped better with a linear than a non-linear amplification; alternatively, a young active adult exposed to various and not stable acoustic environments, with important hearing demands for social interaction, will probably be better helped by a non-linear amplification.

The effect of linearity was observed more frequently through questionnaires than through speech tests, except in the Gatehouse study were many tests were done and results pooled. This has also been reported by other, non-selected, authors.[76]

In clinical practice the number of tests must be limited to avoid attention deficits, excessive travel, and a higher cost of the audiological testing. It is more efficient to use questionnaires which report more often significant changes between two hearing aids.

2.4.4 Compression parameters

Changes of compression parameters do not have the same impact on all subjects, depending on their personal and environmental characteristics. The slow acting release of compression can be regarded as a safe option. But the fast acting release of compression often gave either optimal or poorer intelligibility for different individual listeners.

2.4.5 Other hearing aids parameters

Technologically complex digital HA with directional microphones were preferred and scored better in subjective and objective outcome measurements in some of the selected studies.

Other authors have studied these parameters and have reported divergent results. Digital treatment scored better in questionnaires in some studies.[26, 77-79] However, other authors did not find a difference between the two sound treatments.[27, 80] In some cases an analogue HA may be more suitable for a person than a digital one and not only for the cost/effectiveness aspect.[79] Parving,[28] also showed a lack of difference between the benefits obtained with low and high cost digitally controlled HA on questionnaires of 14 325 subjects.

The study of van Toor demonstrated that technological complexity is not clearly related with high levels of improvements for the subjects.[6] The technology is sometimes so complex that it becomes very difficult to predict what will happen when a parameter is changed. The interactions between the number of channels, the compression parameters, the noise reduction systems, etc. are difficult to predict for all patients.

Lastly, directional microphones provide additional hearing benefit in noise in comparison with omnidirectional microphones as demonstrated by Ricketts. Bergeron showed in a systematic review a moderate level of evidence that the directional microphone has more advantages than the omnidirectional.[38] However, few subjects prefer the omnidirectional to the directional configuration.[35, 81, 82]

A hearing aid should offer the possibility to use a directional microphone to help the subjects exposed to noisy environments as frequently experienced in normal social and professional conditions in active subjects. An aged subject living, always lving in a quiet environment may be helped sufficiently with an omnidirectional microphone**.**

2.4.6 Utilization of HA in real life

Our review concerned only the comparative efficacy/effectiveness of different hearing aids. Other studies have analyzed the HA utilization in real life settings. They showed that the rate of non adherence to HA use is high: up to 30 to 70% of patients who receive HA do not continue to use their aids over time.[50, 72, 83, 84] The rate is related to noise tolerance.[85] Five percent of HA in elderly were found to be in less than ideal operating conditions: dead battery, cerumen occlusion, switched off, etc.[72, 84] The HA use and the consequent benefit can be significantly increased through counselling.[72, 83]

2.4.7 Other considerations

Our review included only RCTs in order to base recommendations on the highest quality evidence. Some previous reviews have been performed with less stringent inclusion criteria. Although most of their authors underlined the lack of well-designed studies, we present in the appendix to this chapter their most relevant results.

Our results are quite consistent with these reviews: the discrepancy of results between tests done in laboratory and questionnaires is often reported. In general, non-linear HAs are preferred to linear ones and digital HAs are preferred to analogue ones, but again evidence of benefit is weak. The reviews also reported that directional HA produce improved hearing performances over omnidirectional HA, although the listening environment influences greatly such performance.

2.5 CONCLUSIONS

For this systematic review of high level evidence for the efficacy of HA, we included 15 publications corresponding to nine randomized controlled clinical trials. The methodological quality of these RCTs is moderate to low. Comparisons between studies are difficult due to the large variations in inclusion criteria, studied hearing aids and outcome measures.

Nevertheless, the following trends were found:

- Non-linear amplification is frequently better scored than linear amplification, but with important inter-subjects variability.
- Better performance of linear amplication is observed in patients with flatter sloped audiological tests, greater dynamic ranges, less varied lifestyles and acoustic environments. Hearing aid fitting should therefore take into account the real-life conditions of the patients.
- Slow compression release time is the safer option for the majority of subjects.
- Directional microphones provide better hearing performance in noise than omnidirectional and behind-the-ear HA.
- More complex HA digital processing are often better scored but with differences between studies due to difference in the population analysed.
- Questionnaires are more sensitive than speech tests to detect different performance comparing two HA conditions.
- The ideal hearing aid should be adapted to different environmental conditions and patients' lifestyle.

Key points

- **The available literature on clinical efficacy and effectiveness of HA is not sufficient to allow evidence-based recommendations.**
- **The methodological quality of studies retrieved is generally low. Moreover, studies are very heterogeneous preventing the pooling of results: variations in patient inclusion criteria, variations in HA analysed or incomplete description of HA and variations in outcome measurements.**
- **The non-linear amplification, the digitally controlled HA fitting and the multiplicity of channels - microphone possibilities - compression choices are shown to improve some efficacy and effectiveness measurements, but with large variations according to patient characteristics.**
- **Compression parameters must not only be selected on the basis of patient audiological measurements, but also taking into account age, hearing demands, cognitive capacity, lifestyle and environments.**
- **Questionnaires on hearing-related quality of life or self-rated communication abilities (HHIE, APHAB, GHABP, PHAP, GHSI, etc…) detect more frequently score differences than the speech recognition tests.**

3 ECONOMIC EVALUATION OF HEARING AIDS

3.1 INTRODUCTION

The aim of this chapter is to assess the cost-effectiveness of hearing aids through a systematic review of full economic evaluations. We defined the term "full economic evaluation" as an analysis that compares both costs and outcomes of at least two health care programmes (definition Drummond et al.[86]

Two types of full economic evaluations were found: cost-effectiveness analyses and cost-utility analyses. These economic evaluations differ in the way they measure outcomes of compared programmes. In cost-effectiveness analyses, outcome data are quantitative and are defined in terms of final endpoints such as life years gained, or in terms of intermediary outcomes such as, for example, improving in speech recognition for hearing impaired persons. In cost-utility analyses, outcome data are measured in terms of life years gained adjusted for the quality of life during this time, using a measure such as quality adjusted life years (QALYs). Thus, this kind of analysis takes both morbidity and mortality into account.

3.2 METHODS

3.2.1 Literature search strategy

We conducted an extensive search in several bibliographic databases. In addition, references of selected studies were also hand searched to retrieve additional publications. Details about the search strategy can be found in the appendix to this chapter.

In total, 334 different articles were retained after this search (see Figure 42 in appendix to this chapter).

3.2.2 Selection criteria and method

The search was limited to papers published between January 1995 and February 2007 and written in English, Dutch or French. A first selection was based on abstracts. Only full economic evaluations which assessed an incremental cost-effectiveness ratio (ICER) were retained as appropriate study designs.

A single economist assessed all abstracts for relevance. Full papers were retrieved and assessed for all potentially relevant studies.

3.2.3 Data extraction and quality assessment strategies

Data were extracted using a structured data extraction form (see appendix to this chapter) and quality was assessed by a single economist using a standard quality assessment checklist for economic evaluations (see appendix to this chapter).[86]

3.2.4 Conversion in Euro 2006

All costs were transformed into prices of 31 December 2006 for each country using Consumer Price Indices. Then we applied the Purchasing Power Parities (PPP) index to obtain comparable costs in Euro among the different countries. The PPP used correspond to 2006 Euro for the 25 member states of the European Union. (Sources: Eurostat and OCDE). For most studies, however, the year of costs was not reported. Therefore, we had to use the related year of publication instead. Costs reported by the studies without transformation can be found in the appendix to this chapter.

3.3 RESULTS

3.3.1 Included studies

From the 25 studies selected by abstract, 3 studies duplicated findings from Joore at al.[87] using data originating from the same trial,[88-90] 11 studies assessed only the effects of hearing aids,[28, 38, 57, 66, 91-97] 2 studies assessed only the costs of hearing aid fitting,[98, 99] 2 studies were willingness to pay analyses,[100, 101] and 1 study was a review of effectiveness studies.[102] Finally, 6 studies were eligible for inclusion in the review: 5 primary full economic evaluations,[87, 103-106] and 1 review of economic evaluations.[59] The flow diagram of inclusions and exclusions is shown in Figure 42 in appendix to this chapter.

3.3.2 Data analyses and synthesis

3.3.2.1 Primary economic evaluations

Among the five primary full economic evaluations, two studies were cost-effectiveness analyses,[105, 106] and three were cost-utility analyses.[87, 103, 104] Key data extraction for each selected economic evaluation is provided in appendix to this chapter. Their quality was assessed following the quality assessment checklist and is also described in the appendix to this chapter.

One economic evaluation compared HA fitting to the situation before HA fitting,[87] one economic evaluation compared different types of HA,[105] and three studies assessed the impact of counselling on the ICER.[103, 104, 106] Table 9 shows an overview of these five primary economic evaluations.

Table 9: Primary economic evaluations.

Type of study	Assessment		
	Comparison of HA	Before and after HA fitting	Impact of counselling
Cost-effectiveness analysis	Newman 1998[105]		Vuorialho 2006[106]
Cost-utility analysis		Joore 2003[87]	Boas 2001[104] Abrams 2002[103]

HA fitting

Joore et al.[87] assessed the cost-utility of HA fitting comparing the situation before and after the HA fitting. They used a Markov model to estimate the ICER of HA fitting for a lifetime period and from a societal perspective. Except mentioning that 79% of patients were fitted with behind the ear HA, characteristics of HA studied were not specified. The study found the effect of HA fitting on the generic health-related quality of life not to be significant. So we can not conclude that HA fitting is a cost-effective alternative compared to no fitting. In the worst case scenario, HA led to higher costs and lower QALYs. Moreover, a comparison between different types of HA should be made to determine the impact of HA characteristics on the ICER. Table 10 shows an overview of characteristics and results of this study.

Table 10: HA fitting.

Author	Intervention (population)	Time frame	Effectiveness		Costs*		Average cost-effectiveness*
			Type	Results (gain)	Type	Results (95% CI)	
Joore et al.[87]	HA versus before HA (Adults without HA experience)	Lifelong	QALY based on:		Direct Health care costs and productivity gains	€897 (563 - 1,375)	
			EQ-5D	0.05 (ns)			€18 158/QALY
			EQ-5D VAS	0.03 (ns)			€27 276/QALY
			Hearing-related VAS	0.44			€2 021/hearing QALY

*Sources : Consumer Price Indices : OCDE / PPP : Eur25 = 1 for 2006 (Eurostat)
HA = Hearing Aids; QALY = Quality Adjusted Life Year; VAS = Visual Analog Scale

HA comparisons

Newman et al.[105] assessed the cost-effectiveness of three types of HA: a one-channel linear conventional analogue HA, a 2-channel non-linear HA and a 7-band 2-channel digital signal processing HA. They conducted a prospective clinical trial to estimate the ICER for a minimum of 4 weeks period for each HA.

As outcomes, they assessed two laboratory measures: the audibility index (AI), calculated using the "FONIX FP40D Real Ear/Hearing Aid Analyzer", allowing to obtain insertion gain by comparing unaided and aided measurements, and the speech perception in noise (SPIN) test including 25 high-predictability (HP) items and 25 low-predictability (LP) items. They also analysed three self-report measures: the abbreviated profile of hearing aid benefit (APHAB), the hearing handicap inventory (HHIE) and the Knowles hearing aid satisfaction survey. The APHAB measured communication function and hearing disability. The HHIE measured the hearing related quality of life by quantifying emotional and social/situational problems. Finally, the Knowles hearing aid satisfaction survey measured consumer satisfaction and computed two sub scores: satisfaction with sound quality features (SQ-Sat) and satisfaction in different listening conditions (LC-Sat).

Both costs and outcomes were discounted at 5% per year. It should be noticed that in this study, patients had to have at least one year of continuous HA experience to be included in the study so they were experienced HA users. The authors concluded that the one-channel linear conventional analogue HA was the most cost-effective intervention (mainly because of the lower cost) and that the 2-channel non-linear HA is the most cost-effective HA among the tested HA. However, in almost all the tests performed, differences in outcomes for the three HA were not statistically significant. It is thus not correct to conclude that the 2-channel non-linear HA is the most cost-effective HA among the tested HA. However, effects on the generic health-related quality of life were not measured. Table 11 shows an overview of characteristics and results of this study.

Table 11: HA comparisons.

Author	Intervention (population)	Time frame	Effectiveness		Costs*	Average cost-effectiveness*	
			SPIN-LP	HHIE/A	Retail price	SPIN-LP	HHIE/A
Newman[105]	HA-A : one-channel linear conventional analogue HA vs before HA (Adult with HA experience)	At least 4 weeks / HA	24	12.1	€1231	€51/point	€102/point
	HA-B : two-channel non-linear HA vs before HA (Adult with HA experience)		32	14.8	€1715	€54/point	€116/point
	HA-C : 7-band 2-channel digital signal processing HA vs before HA (Adult with HA experience)		34	16.7	€3856	€113/point	€231/point
			Incremental effectiveness		**Incremental costs***	**Incremental cost-effectiveness***	
			SPIN-LP	**HHIE/A**	**Retail price**	**SPIN-LP**	**HHIE/A**
	HA-B vs HA-A		8	2.7	€483	€60/point	€179/point
	HA-C vs HA-A		10	4.6	€2625	€262/point	€570/point
	HA-C vs HA-B		2	1.9	€2141	€1070/point	€1127/point

*Sources : Consumer Price Indices : OCDE / PPP : Eur25 = 1 for 2006 (Eurostat)
HA = Hearing Aids; vs = versus

Impact of counselling

Abrams et al.[103] assessed the impact of counselling on the ICER through a randomized clinical trial. The time window of the study was not entirely clear from the publication. Costs seem to be assessed for a 4 weeks period and QALYs (derived from SF36 measures) for a lifelong period. The ICER of HA fitting compared to the situation before HA fitting was €59/QALY and the ICER of HA fitting associated with counselling compared to the situation before HA fitting was €31/QALY. So, authors concluded that HA with counselling was more cost-effective than HA alone. However, in this study, QALYs were estimated from SF36 measures and not directly from utilities. Thus, they did not consider all aspects of health-related quality of life. Therefore,. the very low cost-effectiveness ratio obtained in this study has to be use with caution. Moreover, uncertainty about parameters was not tested. Finally, we can easily assume that the type of HA studied had a significant impact on the effect of counselling. Unfortunately, this impact of HA characteristics was not assessed in this study.

In the study of Boas et al.[104] the impact of counselling was evaluated using a Markov model for a lifelong period and from a societal perspective. Two health care programmes were compared: a HA fitting programme with and without counselling. HA characteristics were not described. Results showed that for a lifelong period, HA fitting associated with counselling compared to the situation before HA fitting led to a better ICER than with HA fitting alone compared to the situation before HA fitting (€20 730/QALY versus €24 300/QALY). But, although a sensitivity analysis was performed in this study, key parameters like extra costs or extra effects of counselling were not varied. Moreover, the impact of HA characteristics on the effect of counselling was not investigated. It should also be noted that, according to the sources for outcomes measure,[87, 88] the effect of HA fitting on the generic health-related quality of life was not significant. Therefore, Boas' findings are not significant.

Vuorialho et al.[106] assessed the impact of counselling on costs and outcomes of HA fitting through a prospective clinical study. Among HA studied, 51% were digital and 46% were analogue. For 3 % of them, no information was given. Patients had no prior HA experience. The ICER of HA fitting associated with counselling compared to HA fitting alone was €443 per additional regular user. They also assessed the effect of HA fitting associated with counselling compared to HA fitting alone on the hearing-related and generic health-related quality of life. The effect, however, was not significant. Therefore, it is wrong to conclude that benefits due to better HA use increased through counselling. Moreover, as in the other studies, the impact of HA characteristics on the effect of counselling was not tested.

Table 12 shows an overview of characteristics and results of these three studies.

Table 12: Impact of counselling.

Authors	Intervention (population)	Time frame	Incremental effectiveness		Incremental costs*		Incremental cost-effectiveness*
			Type	Results	Type	Results	Results
Abrams[103]	HA versus before HA HA + counselling vs before HA (Veterans without HA experience)	QALY : lifelong Costs : 4 weeks?	QALY	NC	Direct and indirect costs	HA : €1034 HA+counselling:€ 1095	HA : €59/QALY HA + counselling : €31/QALY
Boas[104]	HA versus before HA HA + counselling vs before HA (Adults without HA experience)	Lifelong	QALY	NC	Direct health care costs	NC	For the age group of 61-64 : HA : €24 300/QALY HA + counselling : €20 730/QALY
Vuorialho[106]	HA + counselling vs HA (Patients without HA experience; age : 47-87)	1 year	Regular users	+ 16% (16/98)	Direct cost of counselling	€7086	€443/additional regular user

*Sources : Consumer Price Indices : OCDE / PPP : Eur25 = 1 for 2006 (Eurostat)
HA = Hearing Aids; vs = versus; NC = Not communicated

3.3.2.2 Reviews of economic evaluations

One review of economic evaluations was identified.[59] This systematic review was based on three economic evaluations, four cost analyses, and one willingness-to-pay analysis (see Table 13). Among the three economic evaluations, only the study of Mulrow et al was not investigated in our review, and this, because of its year of publication (<1995). As the study of Joore et al. and Mulrow et al. compared HA fitting to the situation before the HA fitting, effectiveness was estimated from improvements in HHIE scores. The ICER was (Eur25) €258/hearing related QALY. The incremental gain in terms of generic health-related quality of life was not estimated.

Palmer et al. assessed the effectiveness of HA in terms of willingness to pay. Users were asked to assign dollar value on sound quality. They concluded that the average increase of perceived value per each one percentage point increase in sound quality was (Eur 25) €8.7. Costs analyses were not further developed in this chapter because they are very specific to the country studied.

Taylor et al. concluded from this review that only few studies, of relatively poor quality, compared digital and analogue HA, stressing the need to conduct good quality trials. They added that the ICER of digital compared to analogue HA was highly sensitive to the cost of digital HA.

Table 13: Review of economic evaluations.

Author	Years	Economic evaluations	Cost analysis	Willingness to pay analysis
Taylor[59]	2001	Mulrow 1990, Newman 1998, Joore 1999	Davis 1995, Lamden 1995, Parving 1997, Reeves 2000	Palmer 1995

3.4 DISCUSSION AND CONCLUSIONS

Examination of the identified cost-utility analyses learned that HA fitting improved the hearing-related quality of life at an acceptable cost compared to no fitting, and that counselling led to more regular HA use. On the other hand, no impact on the generic health-related quality of life was demonstrated, neither in cost-utility analyses comparing HA fitting with no fitting nor in cost-utility analyses assessing the impact of counselling. Such results can be explained by the use of the EQ-5D instrument, in which the audition dimension is not measured. Indeed, two recent studies determined that the cost-effectiveness ratio was highly influenced by the instrument used. They also highlighted that with the HUI-3, a significant impact on the generic health related quality of life could be found, since this instrument includes a dimension on hearing problems.[16, 17]

The only study which compared different types of HA showed that the ICER was mainly cost sensitive, implying little impact of technical features on generic health-related quality of life.

The validity of these studies can be questioned for several reasons.

- Most studies did not assess the impact of HA characteristics on results. Simply comparing HA fitting to the strategy of "doing nothing" is insufficient. To be complete, an economic evaluation should assess all the relevant alternatives. Comparing different type of HA is thus a minimum requirement to correctly conduct an economic evaluation. Among selected cost-effectiveness studies, only one compared different types of HA and little impact of HA technical features on generic quality of life was shown.[105]
- The impact of daily utilization time of the HA on the ICER was also not analyzed.

- The impact on the generic health-related quality of life was not demonstrated. Most studies did not evaluate the impact of HA fitting on the generic health-related quality of life in terms of QALYs and, when it was assessed, the impact was usually not significant. Non significant impact on the generic health-related quality of life can be explained by the fact that it was assessed by the EQ-5D in which the audition dimension is not measured.
- The studies were often based on direct short-term health care costs only. Long-term costs were rarely assessed. The non inclusion of indirect costs or non health care costs like transportation costs can be justified by the fact that they are not important. Productivity loss was also not included due to the fact that most patients were retired.
- Finally, no study assessed Belgian costs. Therefore, the external validity of the studies may be limited.

In conclusion, this literature research did not confirm the cost-effectiveness of HA. Relatively few studies have been performed and important points were often not assessed. Given the limitations of the selected studies in terms of quality and relevance to our research, no evidenced-based conclusions can be made.

Key points

- **Relevance and quality of studies assessing the cost-effectiveness of HA were too limited to allow evidence-based recommendations.**

Major weaknesses are:

- **Few cost-effectiveness analyses compared different types of HA according to their characteristics.**
- **Few cost-effectiveness analyses showed a link between gain in hearing and gain in health-related quality of life, possibly due to the instrument used to measure the health-related quality of life, i.e. the EQ-5D instrument, that does not include the audition dimension.**

4 HEARING AIDS INVENTORY IN BELGIUM

In this chapter, the different hearing aids available on the Belgian market and their sales prices will be discussed. The technological characteristics will be discussed for the most commonly sold HA on the Belgian market. An original complexity scale is elaborated to compare the different hearing aids. The inventory was performed in June 2007.

4.1 RATIONALE

An inventory including the most representative products on the Belgian market serves two main purposes:

To compare public reimbursement and market prices for commonly sold products with the aim to assess the current importance of patient co-payments.

To identify a representative product basket that can be used as a baseline for international price comparisons.

4.2 METHODOLOGY

4.2.1 Data collection

In Belgium, a lump sum is reimbursed to any patient acquiring a HA but the specific product delivered and its price are not registered by the Belgian public third party payer (RIZIV-INAMI) nor the various sickness funds ("mutualities"). Information about the hearing aid types sold and the prices paid by the patients was therefore not available.

To collect this information we contacted the main importers of hearing aid devices on the Belgian market to know which kind of hearing aids they have sold in Belgium in recent years.

These companies were very collaborative in offering information about sold products, most frequently sold HA, and the technological characteristics of the HA. In spite of this good collaboration their overview of technological characteristics was not always complete. The websites of various HA manufacturers were used for completing the technological information. There appears to be no minimum technological standard for devices to qualify for public reimbursement and the information we obtained is often more suited for commercial purposes rather than scientific analysis. To ensure that the collected technological data were complete and correct we asked the companies to check the encoded data concerning their specific HA.

4.2.2 Classification of hearing aids by technological features

The HA market offers a multiplicity of HA with sometimes very few differences between HA characteristics. The variations in HA characteristics could be compared to all possible options of a car. In order to understand the HA market, we propose two types of HA classifications:

- A first classification, using four levels of complexity, is used by HA producers and is described.
- A second classification is developed and proposed by our team. It is more precise and assigns a weight to each aspect of the HA. It should be discussed and validated by producers, retailers, audiologists and ear-nose-throat specialist physicians (ENT). We built this classification proposal because we did not find a HA classification based on technological complexity in the scientific literature nor on the internet. This classification is limited to the HA technological complexity (the physical facts) but includes elements from the literature described in this report and also elements from our own clinical experience. It does not take into account the HA prices.

Contacted audiologists working in other countries had additional information so that we have been informed of the existence of French (Table 14) and German (not received) classifications towards the end of our study.

Table 14: French classification: 'liste des produits et prestations'.

Old French Classification	
A. Efficacy evaluation	
Peak clipping	0-2-4
H-tonality	0-2-4
L-tonality	0-2-4
Compression procedures	0 to 6
Audio input	0/2
Induction coil	0/2
Total A	22
B. Particular characteristics	
Full gain	0-2-4-6-8-10
Gain without distortion	0-2-4-6-8-10
Internal noise	1-2-4-6-8-10
(Position de la pastille ?) (unclear)	10
Battery consumption	0/2
Total B	42
C. Supplementary possibilities	
Programmable	?
> 2 bands	?
Gain progression < 5 dB	?
Recovery frequencies between channels	?
≥ 2 programs	?
Remote control	?
Dual microphone	?
Anti-feedback	?
Auto-adaptative system ? (unclear)	?
New Classification *	
Group A (5 points)	
Group B (8 points, ≥1 suppl possibilities)	
Group C (9 points, ≥3 suppl possibilities)	
Group D (10 points, ≥ 5 suppl possibilities)	

* This classification, developed by an experts panel, will appear soon in the French Law.

4.2.2.1 Four-level classification

This is a classification of HA in four categories with progressive technological complexities, available from the internet and used by different HA producers.

Level I product: basic analogue or digital instruments

The standard analogue or digital hearing aids have linear amplification. The fitting may regulate the maximum output and the amplification of the low and high frequencies. There is generally one channel of treatment. The microphone is omnidirectional.

Level II product: middle-level analogue or digital HA with non-linear amplification.

These hearing aids have compression circuits that automatically adjust the loud sounds coming into the analogue or digital hearing aid (AGC). They provide a non-linear amplification: K-amp, WDRC. They may have two or three spectral channels. There is one microphone with sometimes two openings (omnidirectional or more directional). They may be programmed by a computer, or by trimmers. They allow more flexible utilization than Level I products.

Level III product: advanced instruments

These systems are exclusively digital, allowing the audiologist more fine-tuning capabilities. They may have multiple memories the patient can select depending on the listening situation (restaurant, TV, telephone, music). They may adjust incoming sounds automatically without a volume control. They have two microphones with fixed directionality. They may include noise reduction and fixed feedback corrections systems. They may automatically detect wireless phone, FM systems.

Level IV product: more complex digital technology

These systems include the newly developed systems of microphones with adaptive directionality, complex noise reduction systems, speech recognition systems, adaptive feedback correction systems, adaptive automatic fitting taking account of the usual environment conditions, wireless communication between the two fitted hearing aids, etc…

4.2.2.2 New proposed classification: complexity scale

This classification is more precise than the four-level classification described above. Indeed, the four ordinal categories classification is not always easy to implement because the options offered by the HA are not always comparable and present in one category. These options may be compared to those offered in cars, and it is not always possible to classify various brands of cars.

To limit this difficulty, we propose to give an empirical, albeit arbitrary, value to each technical feature proportionally related to its importance for hearing recovery quality. A weight is assigned to each characteristic and these weights are based on the literature review and on our own clinical experience.

A higher weight is given to the characteristic with the most important impact on hearing recovery quality: amplification types, microphone, noise reduction, feedback reduction. Non discriminant parameters receive a lower weight: the maximum output, the maximum distortion rate. The number of channels received a low weight because the ideal number of channels in not yet clearly defined. The sum of the different weights determines the HA complexity "index". The maximum possible value for this index is 61.

This complexity scale is a first proposal that may serve as a tool to compare the different HA taking into account their functionality for the patients' quality of hearing. This scale should be finalised with the producers, the importers, the audioprothesists, and the users (the patients) in a subsequent stage.

This scale must also be completed by a clear definition of mandatory characteristics that must absolutely be present to define the HA complexity index. Indeed, all the parameters do not present the same importance. This scale must also be compared to the official French HA classification. Until now in France, each HA received a number of points calculated on items A and B of Table 14. This number of points defined the HA official price. This classification is going to be modified. The HA will be classified in 4 groups. The French classification is used to define the HA reimbursement amount for children. For adults, it is also used for reimbursement by complementary insurances.

Table 15 shows the empirical values we have given to the different parameters.

Table 15: Empirical value given to the different parameters to construct the complexity scale.

HEARING AID CHARACTERISTICS	points
Amplification	
Linear (with peak clipping or compression limiter)	5
Non-linear	10
Microphone	
Omnidirectional	1
Directional	2
fixed directionability	5
Adaptative directionability	8
Multiband adaptative directionability	10
Noise reduction	6
Voice enhancement	4
Feedback reduction	
Static	2
Dynamic	4
Average maximum output 90 dB (2cc coupler)	
110-120dB	1
>120dB	2
Maximum distorsion	
>2% for 1 frequency	0
1-2%	1
<1%	2
Equivalent input noise	
10-20 dB	1
>20 dB	0
Channel number	
<3	1
3 to 6	2
>6	3
Number of individual programs	
<2	1
2 to 3	2
>3	3
Environment memory	1
Environment automatic adaptation	1
Induction coil	1
Audio input	1
Second micro to allow M and T together	1
Automatic coil or audio detection	1
Battery life	
<150h	1
150-199h	2
200-250h	3
>250	4
Optimised solution for binaural fitting or wireless detection	2
Music detection and adaptation	2
Wind noise reduction	1

4.3 RESULTS

4.3.1 Hearing aid importers and brands in Belgium

There are three important hearing aid importers in Belgium: Veranneman, Lapperre and Gn ReSound. Each importer offers only a few hearing aid brands. The brands sold by the different importers are:

Veranneman: Widex and Siemens hearing aids.

Lapperre: Phonak, Oticon and Lapperre hearing aids.

Dialogue Gn ReSound: Gn ReSound hearing aids.

According to the Belgian companies' classification by sector, Lapperre is the most important company followed by Veranneman and then by Gn ReSound.

The different importers generally only sell their exclusive brands. There is no competition for a particular brand. The HA are accessible for the patients in ENT centres (usually hospitals), in HA specialized shops or in optician's shops. The HA specialized shops often exclusively represent and sell the products of one importer. Their audioprosthesists may be employees or independent dealers. The specialized shops may also offer all the brands, without exclusivity. About 160 dealers sell HA in Belgium employing over a thousand officially recognized audiometrists.[107]

4.3.2 Most commonly sold HA by importer in 2006 and 2007

All important importers transmitted their best sales (Table 16). The HA categorisation (four-level classification) and price (low, middle, high) was done by the importers. It was not possible to obtain the sales quantities for each HA since all the importers considered that this information was commercially confidential.

Table 16: Most commonly sold HA by importer.

	Price (euros)		4-level classification	Complexity scale
Veranneman				
1. Bravissimo BV9vc	1050	Middle Price	II	24
2. VITA SV9vc	1450	Middle Price	III	41
3. Lotus 13P	500	Low Price	I	15
4. Acuris Life	1750	High Price	IV	48
Lapperre				
1. Phonak Savia 211	2250	High Price	IV	53
2. Phonak Maxx 211D	1300	Middle Price	III	31
3. Lapperre 1400	1300	Middle price	III	37
Gn ReSound				
1. Canta 270	975	Middle Price	II	27
2. ReSound +5 RP60	1475	Middle Price	III	41

4.3.3 Prices of the HA sold on the Belgian market in 2006

It was not possible to obtain detailed data about the quantities of the most commonly sold HA on the Belgian market. Such information was kept confidential by the HA importers while the national health insurance (RIZIV/INAMI) does not record it. Nevertheless, some data were obtained.

In 2006, 44 489 hearings aids were reimbursed by INAMI-RIZIV (communication of INAMI-RIZIV). INAMI-RIZIV reimburses approximately €500 for any type of HA while the retail price is in the range of approximately € 500 to €2475.

According to the UPFI data (National association of Belgian HA importers), the proportion of hearing aids sold in each price category in 2006 was:

- 22.8% of the HA cost <1000 Euros (low cost with assumed low technology HA)
- 36.8% of the HA cost between 1000 and 1500 Euros (middle cost and technology)
- 40.3% of the HA cost >1500 Euros (high cost with assumed high technology HA)

4.3.4 Most frequently sold HA in Wallonia and Flanders

According to the statistic of the Gn ReSound company, the purchase price distribution of the HA is not the same in these two regions (Table 17). The distribution for Brussels was not communicated.

Table 17: Purchase price's distribution in Wallonia and Flanders of Gn ReSound.

	Wallonia	Flanders
Low price	50%	10%
Middle price	30%	30%
High price	20%	60%

The other companies did not communicate similar statistics. They considered that information as potentially useful for the competion. We also contacted some centres. They confirm that :

- In Brussels: HA of low and middle price are mainly sold
- In Flanders: HA of middle and high price are mainly sold

This confirms the distribution communicated by Gn Resound. The middle price HA seems to be the most frequently sold HA in Brussels.

4.3.5 Technological characteristics of selected HA

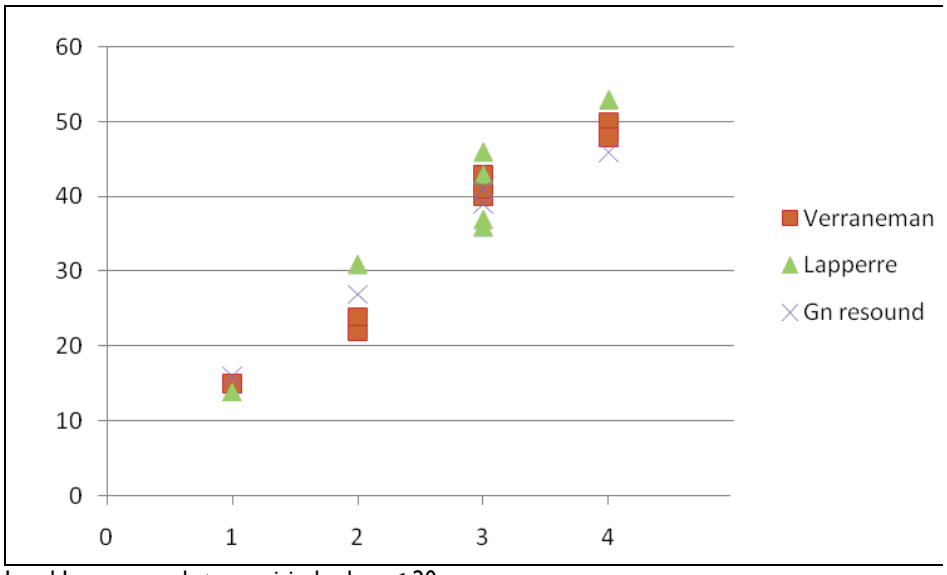
The appendix to this chapter contains a comprehensive overview of the principal characteristics of the studied HA and lists the most frequently sold HA in Belgium.

4.3.6 Comparison between the four-level classification and the complexity scale

Figure 5 shows the relation between the four-level classification (on X-axis) and the complexity scale (on Y-axis), for all the studied HA of the different importers. There is a positive association between the two classifications but this association is not simple.

The level 1 of the 4-level classification contains HA with about the same complexity scale values. The 3 other levels of this classification contain HA presenting a greater variation of complexity scale values. Indeed, the classification into the second or third level is not always easy and they both contain HA with complexity scale values varying between 30 and 40. The limit between the third and the fourth level is also not always very clear.

Figure 5: Four categories score and complexity scale value.

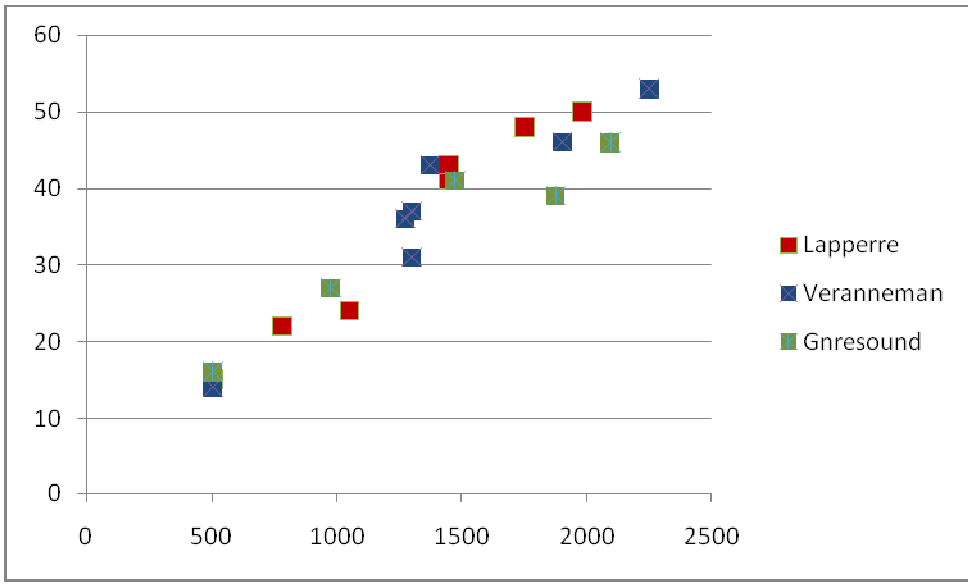


Level I corresponds to empirical values < 20;
Level II to values comprised between 20 and 30
Level III to values comprised between 35 and 45
Level IV to values > 45.The complexity index is more detailed and more precise, and therefore, offers more nuances in the HA classification

4.3.7 Comparison of the prices and the technological complexity of the HA

Figure 6 shows the relation between the HA price (on X-axis) and the empirical complexity's scale value (on Y-axis).

Figure 6: HA price/empirical complexity scale value.

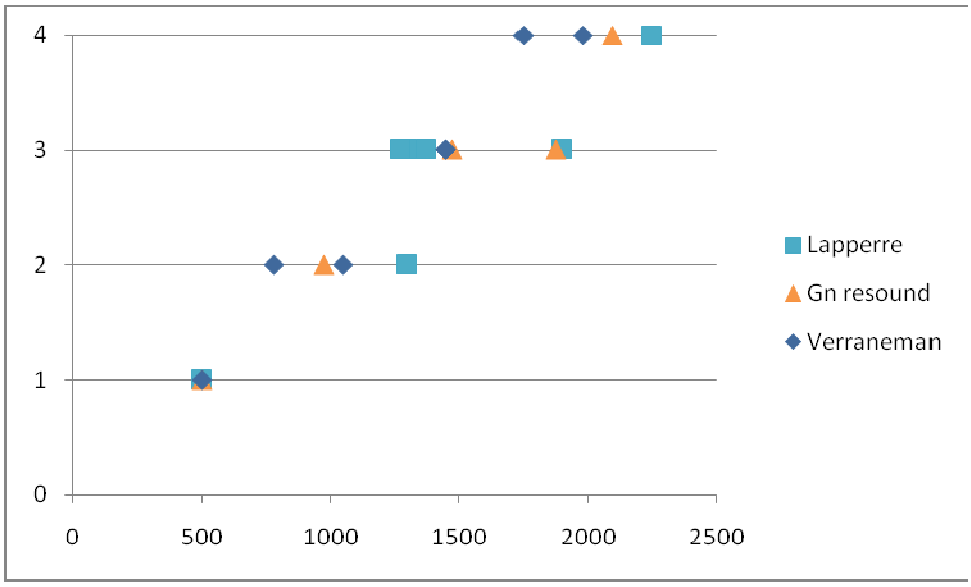


For all the brands, the HA price is positively associated with the empirical value giving the HA complexity. This is observed for all the importers.

The relationship seems to "funnelling out" indicating that variance in technology is increasing with price. The importers offer for the same price hearing aids with significantly different technological complexity. Conversely, the price of different HA with about the same technological complexity sometimes varies significantly.

Figure 7 shows the relation between the HA price (on X-axis) and the four-level classification (on Y-axis).

Figure 7: HA price and four-level classification.



At around €1500 the HA may be in either the II or III category. From around €1800 it is possible to buy a category IV HA. It is possible that the market evolves with complexer HA available now at lower prices. Figure 6 and Figure 7 show that some HA have the same technological complexity with high variations in price. Conversely, other HA sold at the same price present high variations in their technological complexity.

4.3.8 HA inventory

In the HA dispensers' catalogues, the prices of all the HA on the market are ranging from €500 to €2475 (tax included), with an average price of €1473 and a median price of €1450. For the most commonly sold HA, the prices are ranging from €500 to €2250, with an average of €1356 and a median of €1375. It looks like half of the sold and proposed HA are more expensive than approximately €1400. The distribution of the HA prices in the catalogues and of the sold HA is very similar.

A detailed inventory of the HA sold in Belgium with their prices can be found in the appendix to this chapter. They are classified by brands, types, and subtypes. A summary is placed at the top of each importer's brands giving the number of types and subtypes of HA, the number and the proportion of HA in each of the three categories of prices: < €1000 Euros, between €1000 and €1500, > €1500.

4.4 DISCUSSION AND CONCLUSIONS

Some of our observations raise questions. The impossibility to collect data through a single and neutral source was the first limitation to this analysis. The INAMI-RIZIV and mutualities do no collect information on the HA technological complexities and the real prices paid by the patients. Therefore, the information for this chapter was collected from the three most important importers of hearing aids.

The second limitation was the difficulty to find the precise technological features of the hearing aids sold in Belgium. The communicated information by the importers is often more commercial than scientific.

The third limitation was the absence of clear standards for the classification and recording of the hearing aids technological complexity. We tried to remediate this problem by proposing our own complexity scale allowing a more precise comparison between hearing aids than through the 4-level classification used by the producers and importers. It could be considered to start using this scale and to improve it with collaboration of the HA producers, importers, audioprothesists, and the patients' experiences. The complexity scale is more precise but obviously also more time consuming. The four-level classification does not give a clear limit between the categories II - III and III - IV.

Some HA have the same technological complexity with high variations in price. Conversely, other HA sold at the same price present high variations in their technological complexity.

Seventy percent of HA sold are from categories III-IV. The complexity index was higher than 35 for the majority of them. The HA prices are positively associated with the technological complexity for HAs < €1200. Above €1200, an increase of price does not automatically reflect a proportional increase in complexity. The evolution of the HA market may explain this overlapping: new HA with more complex technology are available at lower prices.

The price related statistics of the most frequently sold HA should be presented in three categories: < €1000, between €1000 and €1800 (rather than €1500 because from €1800 onward a category IV HA is available) and > €1800. The Phonak-Lapperre association has the biggest HA catalogue. The smallest catalogue is presented by Gn ReSound.

The most expensive HA seem to be more frequently sold in Flanders and the cheapest products in Wallonia.

For HA sold at a price above €1500, the out of pocket charge for the patient is at least two thirds of HA price. For HA with a price between 1000 and 1500 euros, the out of pocket charge for the patient is at least the half of HA price.

Key points

- **There are no data about prices paid by patients or about the technological complexities of HA sold in Belgium available from NIDHI (INAMI/RIZIV). Most data were retrieved from importers.**
- **Comparing HA is difficult because of a multitude of possible technical options. For this reason we have constructed a HA complexity scale.**
- **At the same price, the technological complexity is variable. Similarly, for the same technological complexity, the price is variable.**
- **Seventy percent of HA sold were of categories III-IV and the complexity index was higher than 35 for the majority of them.**
- **In 2006, HA sold were less then €1000 in 23% of cases, between €1000 and €1500 in 37% and above €1500 Euros for 40% of all sales.**
- **Prices of the most frequently sold HA are ranging from €500 to €2250, with an average of €1356 and a median of €1375.**
- **HA with higher prices are more frequently sold in Flanders.**

5 BELGIAN MARKET STRUCTURE

5.1 INTRODUCTION AND METHODS

The aim of this chapter was to describe the features of the hearing aid industry and to understand the relationships between the main actors in Belgium. When information was available we tried to analyse the value chain system, the competitive environment, the market shares and the price structures of HA in Belgium.

Information about the market structure in Belgium was found from different sources:

- hearing aid manufacturer internet sites (Siemens, Gn ReSound, Oticon, Phonax, Widex, Starkey, etc.)
- hearing aid manufacturer contacts
- importers internet site (Veranneman, Lapperre, Dialogue)
- importers' contacts
- specialized literature
- interviews of ENT and audioprothesist

The analysis was difficult due to the confidential nature of a considerable part of the transmitted information. Companies often refused to exchange key information such as sales numbers, operating profits, marketing expenditures, etc. Annual reports of manufacturer companies were analyzed to obtain such information. However, because hearing aid manufacturing was not the single activity of the related companies, no sufficiently specific information could be isolated from this source.

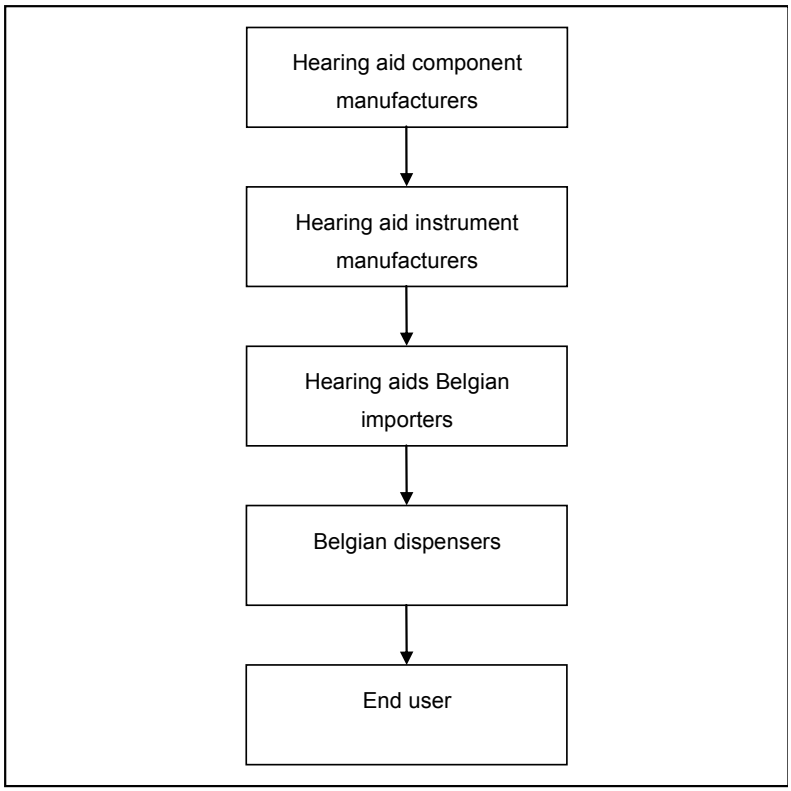
5.2 VALUE CHAIN SYSTEM

The aim of the Porter value chain is to decompose all activities (production, logistics, marketing, …) of an organization that are required to bring a product from its conception to the final end-user and to calculate the value added by each activity. Such an analysis allows the organization to develop a management strategy to maximise the value of the product at a minimum cost and to develop a competitive edge. This concept was then enlarged beyond the organization. The value chain of an organization is part of a larger value chain system including upstream supplier and downstream dispenser and customer.[108]

In this section, we will analyse the hearing aid industry value chain system by detailing the stages required to produce a hearing aid. Details about value added by activities performed by each organization that participated in the production were unfortunately not available.

The hearing aids value chain is relatively simple and can be divided in five tiers: Component manufacturers, hearing aid manufacturers, hearing aid importers, hearing aid dispensers, and end users (Figure 8).

Figure 8: Hearing aid value chain.



5.2.1 Relations between component manufacturers and hearing aid manufacturers

Essentially, hearing aid manufacturers are mainly assemblers or integrators of components. Essential components, as for example microphones, are manufactured by independent suppliers. Only digital amplifiers are mainly produced by the instrument manufacturers.

The two most known hearing aid component manufacturers are the Knowles Company and the Sonion Company.

In the past, the Knowles Company was the single provider of microphones. To counter this monopoly, hearing aid manufacturers developed their own microphones or supported a new microphone producer, the Microtronic Company, which has now become the Sonion Company.[109] However, according to the Belgian hearing aid importers, the Knowles Company is still the global leader in microphone production.

A list of hearing aid component producers and of hearing aid manufacturers can be found on the internet through the site www.medibix.com, entering the search term "hearing aids".

The price at which hearing aid manufacturers buy hearing aid components is unfortunately, but unsurprisingly, not publicly known.

5.2.2 Relations between hearing aid manufacturers and hearing aid importers

The most important hearing aid manufacturers present on the Belgian market are:

- Siemens-Hearing
- Phonak
- Widex
- Gn ReSound
- Oticon
- Lapperre (subsidiary of Phonak since 1996)

The combined market share of these manufacturers for Belgium is 90 % (Source: interview of Belgian hearing aid importers), implying a minimal value of the Herfindahl-Hirschman Index (HHI) of 1620.[d] The US department of justice considers a score between 1000 and 1800 to be indicative of a moderately concentrated market and a score above 1800 pointing to high market concentration).[110] These manufacturers supply the Belgian market via Belgian importers. The main importers in Belgium are Veranneman, Lapperre and Dialogue. Each importer represents one specific hearing aid trademark (Table 18). Veranneman exclusively sells Widex and Siemens trademarks, Lapperre exclusively sells Phonak and Oticon in Belgium, whereas Dialogue Gn resound exclusively sells Gn ReSound. Consequently, Dialogue has to go via Veranneman to obtain Widex and Siemens HA trademarks and via Lapperre to obtain Phonak and Oticon HA trademarks. They can not buy them directly from the manufacturer. Information to determine the costs and values added in this stage is kept confidential.

Table 18: Trademarks by hearing aids importers.

Belgian Hearing aids Importers	Trademarks exclusivity
Veranneman	Widex and Siemens-Hearing
Lapperre	Phonak, Oticon and Lapperre
Dialogue	Gn ReSound

5.2.3 Relations between hearing aids importers and dispensers.

The HA are accessible to patients via different ways:

- Ear, Nose, and Throat (ENT) centres (usually in hospitals via audioprothesists)
- HA specialized shops
- Optician's shops

HA specialized and optician's shops exclusively represent and sell the products of a single importer. ENT centres usually have agreements with one importer and their audioprothesists may be employees or self-employed. Around 160 dealers sell HA in Belgium and the number of audioprothesists increased from 911 in 2001 to 1085 in 2005 (Source: INAMI/RIZIV: http://www.riziv.fgov.be).

Recommended retail prices are determined by importers but each dispenser is in principle free to demand more or less than these prices, which rarely happens. HA prices are relatively fixed with little differences between shops. This could be explained by a tacit agreement between dispensers.

Even while exact numbers are confidential, dispensers seem to be paid a proportion of around 25-40% of the sales price of the HA by the importer (personal communication from an audioprothesist). The three importers in Belgium refused to disclose information on this subject.

5.2.4 Relations between dispensers and end-users

Because of varying degrees of hearing impairment, the multiple HA characteristics, but also the variations of HA use due to different lifestyles of people, the choice of the most optimal HA for a specific patient is very difficult. On the whole, persons with hearing loss are not well-informed consumers. They have difficulties to choose the HA which corresponds best to their hearing impairment and their lifestyle. They have to rely on the dispensers' advice and usually do not make product comparisons.[109] Dispensers, however, have financial incentives to sell high price HA and to avoid fitting basic HA because, as explained above, they are paid a proportion of the HA sales prices.

There are a lot of barriers to the use of hearing aids. First, if not covered by public insurance, the cost of hearing aids is an important barrier. In Belgium, the degree of

[d] The Herfindahl-Hirschman Index is calculated by squaring the market share of each firm in a given market, and then summing the resulting numbers. The HHI ranges from close to zero to 10,000. Assuming the lowest possible market concentration for 5 manufacturers with an aggregate market share of 90% would equate to a uniform market share of 18% for each company; setting the minimal HHI at 5 times the square of 18 equates to 1620.

hearing loss a patient must suffer in terms of decibel hearing loss to qualify for reimbursement is 40 dB at 1000 Hz, 2000 Hz and 4000 Hz for a monaural fitting and 45 dB in the best ear at 1000 Hz, 2000 Hz and 4000 Hz for a binaural fitting (40 dB since July 2008, www.riziv.fgov.be). So, people having a hearing loss degree which does not meet these criteria do not have access to reimbursement and bear the full cost of their HA.

Second, the perception of stigmatization is an important barrier. Some patients are also not aware or do not want to be aware of their hearing loss problem. Moreover, if patients decide to try a hearing aid, the adjustment period and the fact that hearing aids do not correct hearing loss completely can lead to dissatisfaction. Difficulty in use can also lead to disuse of hearing aids.[111-113]

As a consequence, and although the number of people with hearing loss problems is important, the market penetration assessed by the number of hearing aid users divided by the number of persons with hearing loss, is low. According to the hearing aid industry association, the market penetration in the US was about 17.6% in 1980 and about 22.2% in 2001.[111, 114, 115] In Belgium, the market penetration is even lower. It is estimated that 800 000 persons are suffering from hearing loss in Belgium and in 2000-2004 only about 120 000 of them had a hearing aid (personal communication, D. Ghinet, INAMI/RIZIV), i.e. a market penetration of approximately 15%. The biggest strategic challenge the hearing aid industry faces is the increase of market penetration.

According to data from INAMI/RIZIV on the number of HA reimbursed in 2005, 98.5% of HA reimbursed were for adults (> 18 years) and there was little difference by gender (Table 19).

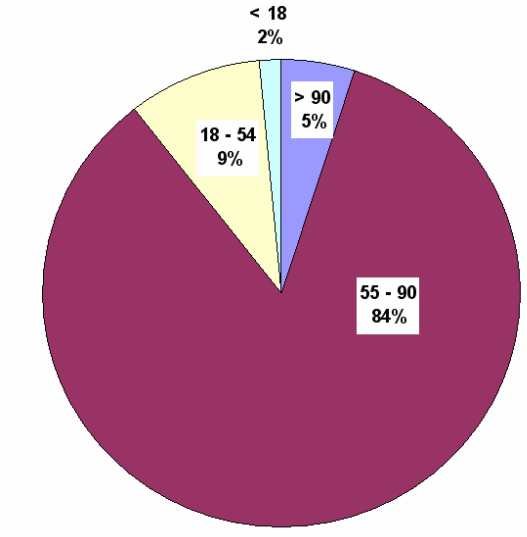
The majority of patients (84%) having acquired reimbursed HA in 2005 were aged between 55 and 90 years old (Figure 9) and 60% of them had a binaural fitting, counting for two devices per patient in our data.

Table 19: Number of reimbursed HA in Belgium in 2005.

	< 18 years	> 18 years	Total
Women	283	22 816	23 099 (53.9%)
Men	350	19 418	19 768 (46.1%)
Total	633 (1.5%)	42 234 (98.5%)	42 867

Source: INAMI/RIZIV billing data

Figure 9: Age repartition of patients having acquired a reimbursed HA in Belgium in 2005.



5.3 COMPETITIVE ENVIRONMENT AND MARKET SHARES

Hearing aid manufacturers are international companies. Most companies were active since the 1950s. From the 1970s on, some new companies like Starkey in 1971 and

ReSound in 1984 entered the market. During the 80s, there were a handful of entries, mainly linked to patented technological innovations (Table 20).[115]

In the beginning of the 1990s, the hearing aid industry was relatively fragmented. The leaders in the hearing aid industry were Siemens and Starkey (with each approximately 20% of market share), followed by Oticon, Gn Danavox, Philips, Phonak, and Widex (each 5 to 10% market share) and finally there were more local companies such as Beltone and ReSound.[109]

Table 20: Most important HA manufacturers during the 90s.[115]

Company name	Founding year	Start of hearing instrument production	Headquarters
Siemens	1847	1910	Germany
Starkey	1963	1971	United States of America
Oticon	1904	1946	Denmark
Gn Danavox, merged into Gn ReSound	1943	1943	Denmark
Widex	1956	1956	Denmark
Philips	1891	1948	The Netherlands
Phonak	1947	1947	Switzerland
ReSound, merged into Gn ReSound	1984	1984	United States of America
Beltone	1940	1940	United States of America

Market shares differed according to the types of hearing aids. In 1993, Siemens was the leader in 'behind-the-ear' (BTE) instruments while Starkey was the leader in 'in-the-ear' (ITE) and 'in-the-canal' (ITC) instruments (Table 21).[115] These data for 1993 would indicate minimal HHI values of 891, 1037 and 1105 for BTE, ITE and ITC hearing aids respectively.

Table 21: World market shares by type of hearing aids in 1993.[115]

Company name	BTE	ITE	ITC
Siemens	24%	14%	12%
Starkey	<5%	29%	31%
Oticon	10%	<5%	<5%
Gn Danavox	9%	<5%	<5%
Philips	7%	<5%	<5%
Phonak	7%	<5%	<5%
Widex	6%	<5%	<5%

Since the early nineties, the industry has become more concentrated due to a series of mergers and acquisitions (sources: literature,[109, 115] company sites, and annual reports), see also Figure 10 to Figure 12:

- Starkey bought Omni Hearing Systems and Nu-Ear Electronics in 1989, acquired Qualitone in 1996 and MicroTech in 1999.
- ReSound acquired Viennatone and 3M hearing health, renamed "Sonar", in 1994. In 1999, Gn Danavox bought ReSound to form Gn ReSound. In 2000, Gn ReSound bought Beltone, which had bought Philips in 1999.
- Oticon further changed the market structure in 1996 by increasing their market share thanks to the acquisition of Bernafon-Maico.
- A&M, a subsidiary of Siemens bought Electone in 1999.

Figure 10: Starkey merger and acquisition activities.

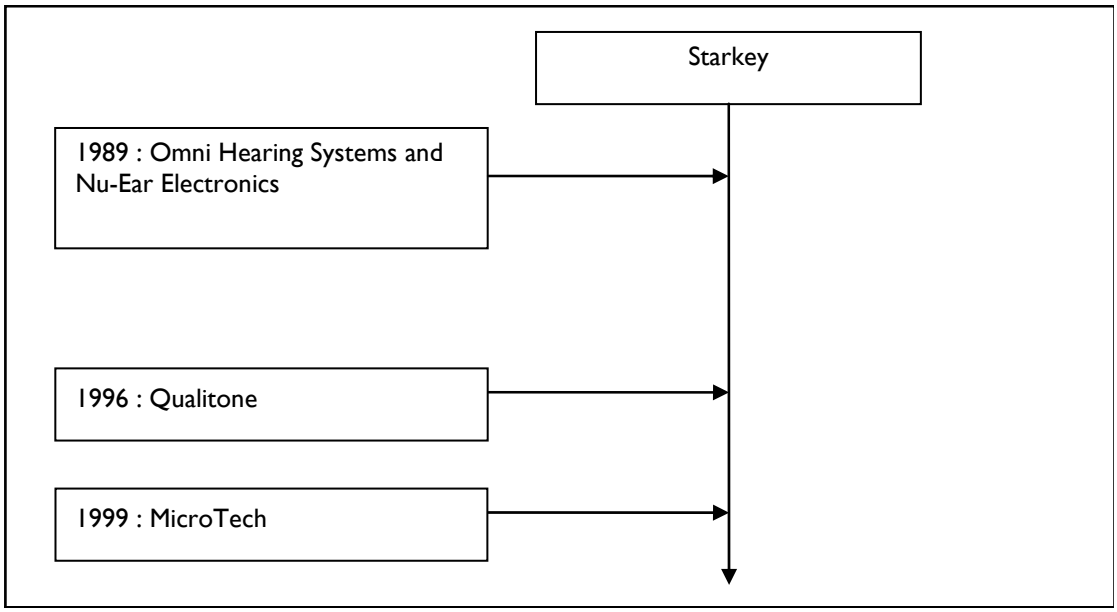


Figure 11: Oticon, Siemens and Widex merger and acquisition activities.

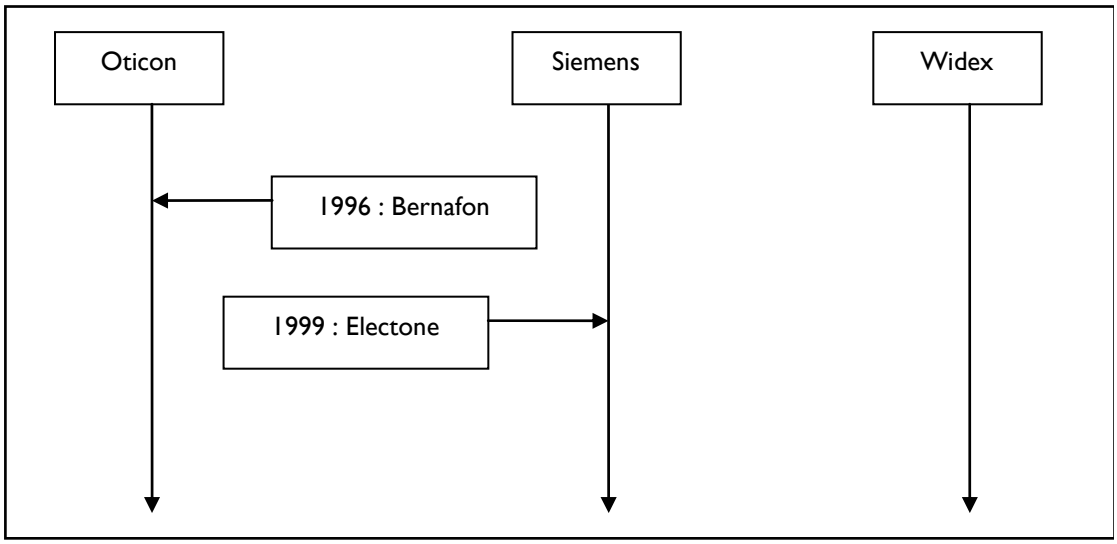
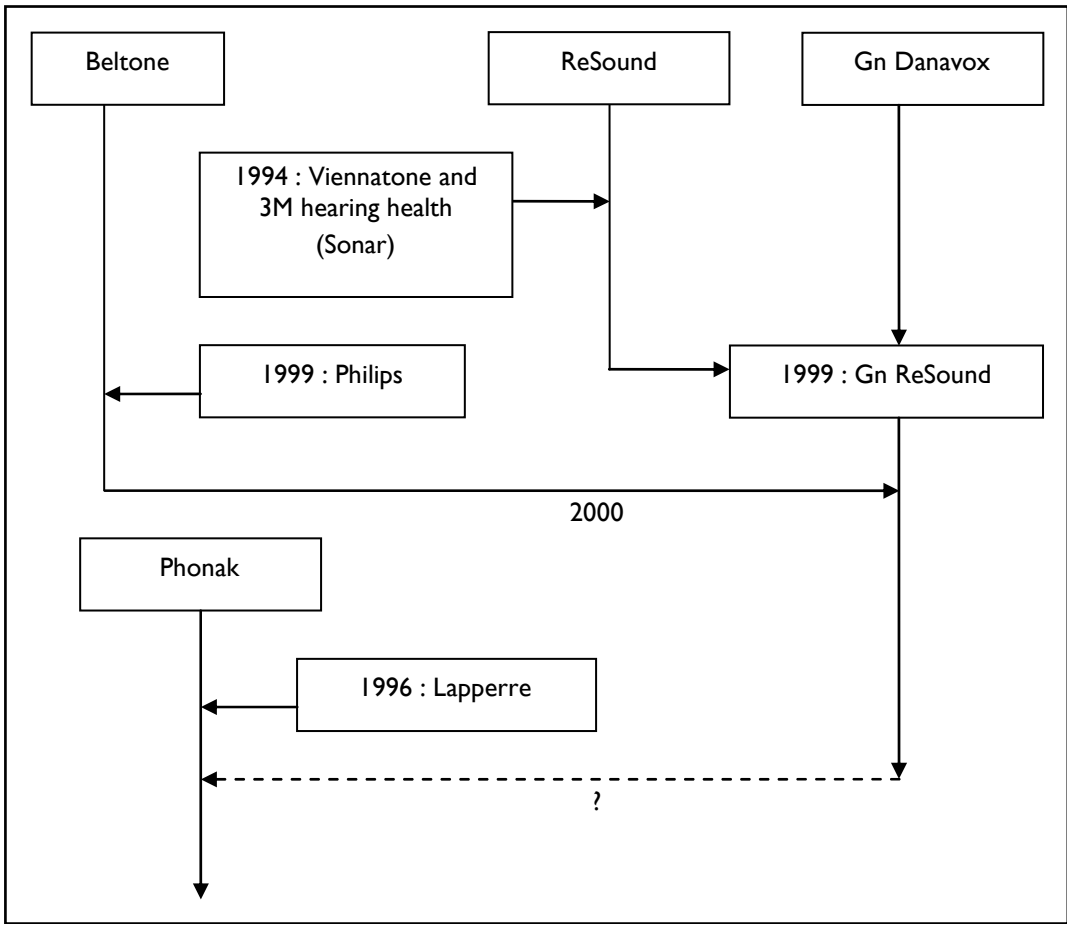


Figure 12: Gn ReSound and Phonak merger and acquisition activities.



As a result, the industry is now dominated by five leaders with around 10-20% market share each: Siemens, Gn ReSound, Starkey, Oticon and Widex. Widex did not engage in any merger or acquisition activities and was the only company increasing its market share thanks to its successful digital technology.

At the end of 2006 Phonak announced its intention to buy Gn ReSound, in which case market leaders would have become Siemens, Phonak, Starkey, Oticon and Widex but this merger was opposed by competition authorities.

The most important BTE hearing aid manufacturers present in Belgium are Siemens, Phonak, Gn ReSound, Widex, and Oticon. Lapperre, a Belgian manufacturer founded in 1948 was bought by Phonak in 1996. We tried to determine Belgian market shares by asking importers the number of hearing aids sold by trademarks but this information was kept confidential.

5.4 PRICE STRUCTURES

5.4.1 Price elasticity

Price elasticity measures the relationship between changes in quantity demand of a product and changes in its price, i.e. the sensitivity of the consumer purchasing behaviour when prices are changed.

$\varepsilon = (\%\Delta Q / \%\Delta P)$

In the previous section, we explained that the market penetration of hearing aids is low. A strategy to increase the market penetration could be to decrease hearing aid prices. However, this may not hold true given the supposed relative inelasticity of the demand function.

In theory, hearing aid demand is relatively inelastic to price due to the following main factors:[111, 116]

- Hearing aids are perceived as necessary goods given their medical necessity for which few substitutes exist.
- Consumers are not well-informed and have difficulties to assess price differences.

As a result, if dispensers reduce hearing aid prices, the impact on the market penetration and on the total revenue should in theory be low. However, the low penetration rate of hearing aid use in Belgium, even among people who qualify for reimbursement of basic HA (see also chapter 7), provokes the question whether HA are truly perceived as a necessity good by all potential consumers. The relative inelasticity of HA may have to be mitigated on this account.

Finally, it should be noted that the market is led by few competitors (oligopoly). Moreover, the fact that the market is divided between importers who exclusively sell specific trademarks can even be seen as a market structure where each importer holds a monopoly for its trademarks.

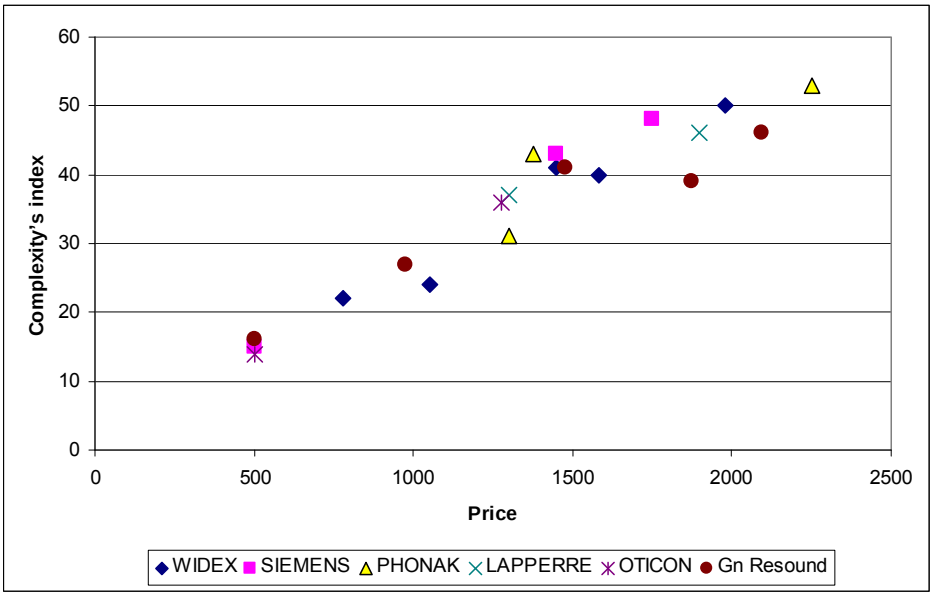
This analysis consequently demonstrates the importance to monitor and regulate practices of the firms.

5.4.2 Price and complexity matrices

As explained in chapter 4, we developed an empirical complexity scale to compare the different HA taking into account their utility for the patients' quality of hearing.

The relation between the HA price and the empirical complexity's index is shown in Figure 13.

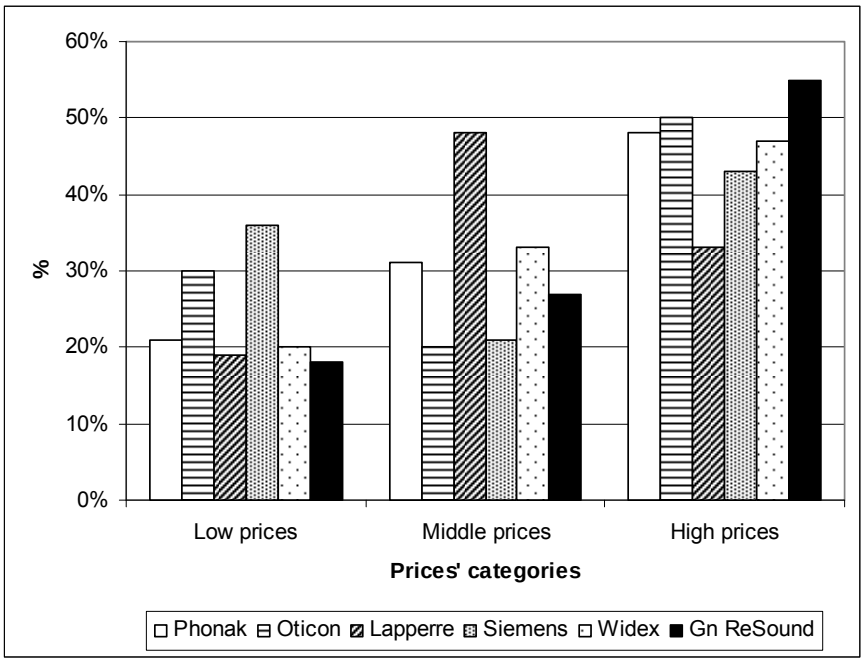
Figure 13: HA price/empirical complexity's index.



We see a linear relation between the price and the complexity of the hearing aids. Basic hearing aids are sold at a low price and high technology hearing aids are sold at high prices. It should, however, be understood that this figure only represents HA discussed in chapter 4. It does not represent all HA sold by manufacturers and does not allow to determine whether one HA manufacturer produces more high technology HA than another.

We also have classified HA in three prices categories (< €1000, €1000 € -€1500, and > €1500). Except for the Lapperre manufacturer, the part of HA with high prices was more elevated than HA with low or middle prices, especially for Gn ReSound (Figure 14).

Figure 14: Price categories repartition by HA manufacturer.



According to the UPFI data (national association of Belgian HA importers), the percentage of hearing aids sold in each price category in 2006 was (see also 4.3.3):

- 22.8% of the HA cost < €1000
- 36.8% of the HA cost between €1000 and €1500
- 40.3% of the HA cost > €1500

Such results could mainly be explained by two factors:

- Audioprothesists have a financial incentive to sell high price HA as they receive a percentage on the HA price (see 5.2)
- Consumers cannot assess themselves which HA corresponds most to their needs (see also 5.2)

One could assume that this situation is attenuated in poorer areas where audioprothesists have to propose basic HA at a low price as people otherwise would not buy them.

5.5 DISCUSSION

The value chain system of the hearing aid industry was impossible to analyze in detail due to the confidential nature of key information. Relationships between the organizations involved in the chain were confusing and the value and cost added in each stage was impossible to determine. Analysis of annual reports, the only information publicly available, did not help us much because most companies are international and equally engaged in business activities beyond the scope of hearing aid manufacturing and marketing.

Analysis of the competitive environment for manufacturers shows that the market could be seen as moderately concentrated in the early nineties and has undergone further waves of mergers and acquisitions ever since.

In addition, little price competition can be observed on the Belgian retail market. Suggested retail prices of HA are published by importers but dispensers are, in theory, free to sell HA at other prices. However, the study showed that, in reality, prices do not vary among dispensers and most HA are of the more expensive type, i.e. priced above €1000 in 2006, over two times the established public reimbursement lump sum. This can mainly be explained by the following factors:

- On the supply side:
  - The market is an oligopoly, obstructing normal free market mechanisms to some extent.
  - Audioprothesists receive a proportion of the HA prices.
- On the demand side:
  - The demand is relatively inelastic to price

However, dispensers also provide a low price HA equal to the amount reimbursed by the RIZIV/INAMI in order to be able to capture the demand of those consumers who would lack sufficient means otherwise or are less willing to pay.

Key points

- **The market structure is difficult to analyse due to the confidential nature of key information.**
- **The global market for hearing aids could be seen as moderately concentrated in the early nineties and has undergone further concentration ever since. Because of this evolution the hearing aid market is currently an oligopoly, obstructing normal free market mechanisms to some extend. As a result there is little price competition among dispensers.**
- **Dispensers of hearing aids in Belgium are paid an undisclosed proportion of the hearing aid price by the importer, leading to a financial incentive to sell high price hearing aids.**
- **The most frequently sold hearing aids in Belgium are expensive, on average over two times the established reimbursement lump sum.**

6 INTERNATIONAL COMPARISON

6.1 INTRODUCTION AND METHODS

The aim of this chapter is to compare HA reimbursement schemes and HA prices among European countries. Prices of Belgian HA described in the inventory in chapter 4 will be compared to prices of the same HA sold in other countries. Such a comparison will allow us to assess price variability for HA, which are products that are manufactured in a standardized manner and marketed in the global marketplace. Because of this, one would expect relatively small price differences across countries. Again, our comparison will focus on hearing aids in adults.

We applied the Purchasing Power Parities (PPP) index to obtain comparable prices in Euro among the different countries. The PPP used correspond to 2006 Euro for the 25 member states of the European Union (Sources: Eurostat). In this chapter, these prices will be preceded by the symbol Eur25.

Public reimbursement rules and HA prices of the analyzed countries came from the following sources:

- Hearing aid manufacturers internet sites and contacts (Siemens, Gn ReSound, Oticon, Phonax, Widex, Starkey, etc.)
- Hearing aid dispenser sites and contacts
- National health insurance internet sites and contacts
- Specialized literature,[117, 118] and internet site (http://hear-it.org/)
- Interviews with ENT specialists

When various sources were contradictory we selected the most reliable (i.e. official sources) and the most recent sources.

6.2 HEARING AID PROVISION AND REIMBURSEMENT COMPARISON

6.2.1 Belgium

Patients with hearing impairment have to visit an ENT specialist to obtain a prescription for a HA test. With this prescription, they visit an audioprothesist who carries out a series of audiologic tests and provides the HA for a trial period. After approximately two weeks, patients go back to the ENT specialist with the results of the audiologic tests. If patients are satisfied with the HA, the specialist gives them a prescription allowing for reimbursement by the national health insurance (INAMI/RIZIV).

For adults, the lump sum reimbursed amounts up to €484 (Eur25: 472) for monaural fitting and €957 (Eur25: 933) for a binaural fitting (January 2008). For children (up to the age of 18 years), the lump sum reimbursed is € 824.99 (Eur25: 804) for monaural fitting and €1,634.12 (Eur25: 1,593) for a binaural fitting. Once a HA is out of warranty (usually after five year), patients have to pay for maintenance and repair.

INAMI/RIZIV allows patients to renew their HA every five year for adults and every three year for children. However, if the hearing loss worsens at least 20dB at 1000, 2000 and 4000 Hz, no delay is required.

For monaural fittings, only patients having a hearing loss of at least 40 dB at 1000 Hz, 2000 Hz and 4000 Hz, and with an auditory gain of 5 dB for the speech index[e] or a gain of 5% in speech intelligibility[f] measured without noise are eligible for reimbursement.

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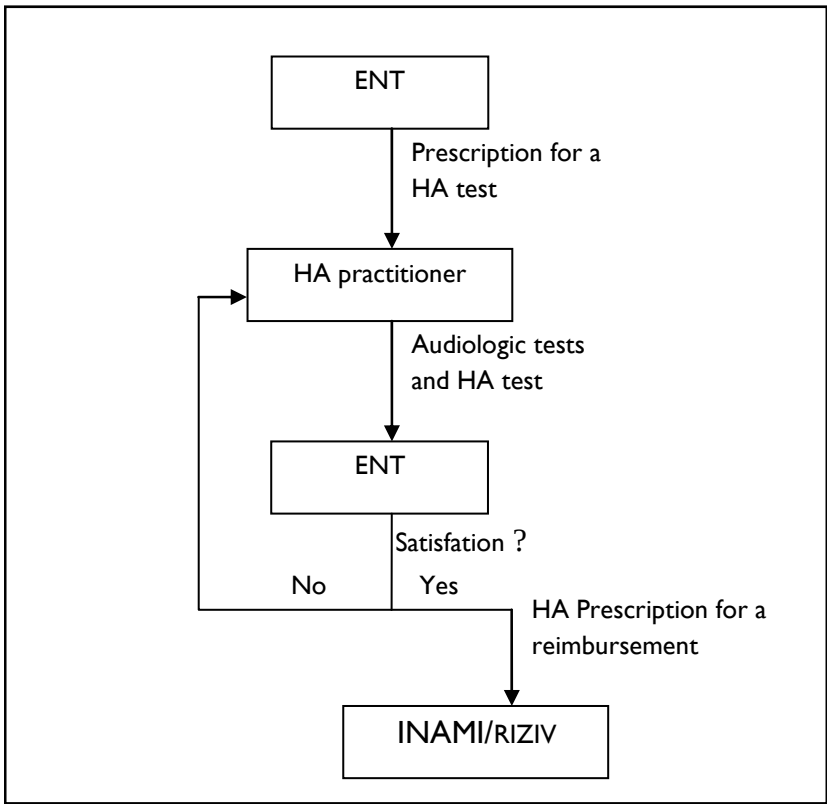
[e] The speech index is the intensity in dB giving 50% of speech intelligibility

[f] Three methods are available to obtain the speech intelligibility percentage:
1) By measuring the averaged percentage of words correctly repeated at 40, 55 and 70 dB (= Indice de Capacité Auditive).
2) By measuring the intelligibility % recorded from 30 to 90 dB, by step of 10 dB. Each correctly repeated word receives 10% at 30, 40, 80, and 90 dB, and 20% at 50, 60, and 70 dB (Grille d'intelligibilité du bureau

For binaural fittings, a hearing loss of at least 40 dB[g] in both ears at 1000 Hz, 2000 Hz and 4000 Hz, and a supplementary gain of 5 dB for the speech index or a supplementary gain of 5% in speech intelligibility measured without noise are required. Moreover, an improvement of the sound source localization with binaural fitting compared with monaural fitting are required.

It should also be noted that both the Flemish VAPH agency and the Walloon AWIPH agency reimburse FM transmission devices: the AWIPH agency pays €2744 and the VAPH agency pays €2389 (binaurally) (2008 prices). This may have an impact on the type of devices supplied and raises questions about reimbursements when future innovations may see the integration of the FM functionality in hearing aids.

Figure 15: HA provision in Belgium.



6.2.2 France

Patients with hearing impairment in France visit an ENT who performs audiologic tests and gives the patient a prescription for a suitable HA. Then, patients go to an audioprothesist for the HA fitting. Only HA referred in a specific list, i.e. the "liste des produits et prestations remboursables" (LPP), are reimbursed.

Patients below 20 years of age are reimbursed on the basis of the LPP tariffs, varying from €900/HA to €1400/HA. For some patients, such as blind people, specific reimbursements exist. Adults only receive 65% of a lump sum of €199.71, i.e. €129.81 (Eur25: 123). Moreover, for accessories, 65% of the tariffs referred in the LPP are reimbursed. For maintenance charges, 65% of an annual lump sum of €36.59 is reimbursed.

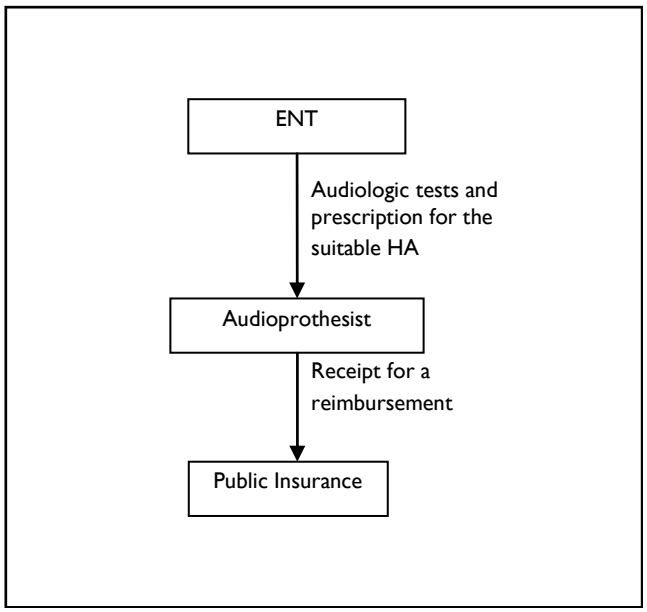
international d'audiophonologie (BIAP)).
3) By measuring the SRT (Speech reception threshold) = the percentage of intelligibility gain at the speech index level of the worse curve.

g It should be noted that since July 2008, a hearing loss of at least 40 dB (and not 45 dB as previously) in the best ear at 1000 Hz, 2000 Hz, and 4000 Hz gives access to a reimbursement

Patients can also have an additional amount through a complementary mutual insurance (up to €600). Patient covered by the "couverture maladie universelle" (CMU) received a maximum of €443.63 (2008 prices) and have the right to a new HA every 2 years.

It is the ENT who decides if a HA fitting is needed and who dispenses the prescription for appropriate HA. No formal condition on hearing loss degree is determined, and hearing aid prices are negotiated between importers and dispensers.

Figure 16: HA provision in France.



6.2.3 Germany

Patients with hearing impairment in Germany have to visit an ENT specialist or a general practitioner (GP) to obtain a prescription for a HA test. With this prescription, they visit an audioprothesist who carries out a series of audiologic tests and provides the HA to test. A detailed description of HA fitting and delivery procedures can be found in various agreements ("Rahmenvertrag") between audioprothesists and statutory insurance funds.[119] An interesting supplementary condition to be found in those agreements stipulates that at least two cheap HA (requiring no patient co-payment beyond the legally foreseen minimal co-payment of €5 to €10) should be tested before returning to the ENT specialist, who then gives a prescription for reimbursement.

Alternatively, patients can acquire hearing aids through so-called "direktversorgung",[120] whereby HA tests and anatomic measurements are performed at the practice of the ENT specialist by specialized staff from hearing aid manufacturers/assemblers (or either by the specialist him/herself who is paid a lump sum by the manufacturer for this service). The hearing aid is then chosen and assembled by the involved manufacturer/assembler and sent to the ENT practice by mail order ("Versandhandel"). Two mail order companies are currently operating on the German market: Auric Hörsysteme and Sanomed/Sonic Innovations.

Typically, only one type of hearing aid is eventually tested. Preliminary advice on various technicalities and according price ranges is offered by the ENT specialist.

In a 2001 report by a major German insurance fund,[121] AOK, indicates that 15% of patients treated by "classical" referral to an audioprothesist are fitted a HA without further patient co-payment. For patients going through the "direktversorgung" this rate would be over 80%. This report also indicated vast price differences (from 1419 Deutsch Mark to 1975 Deutsch Mark) for the same device (Siemens VIVA 703) sold by various audioprothesists.

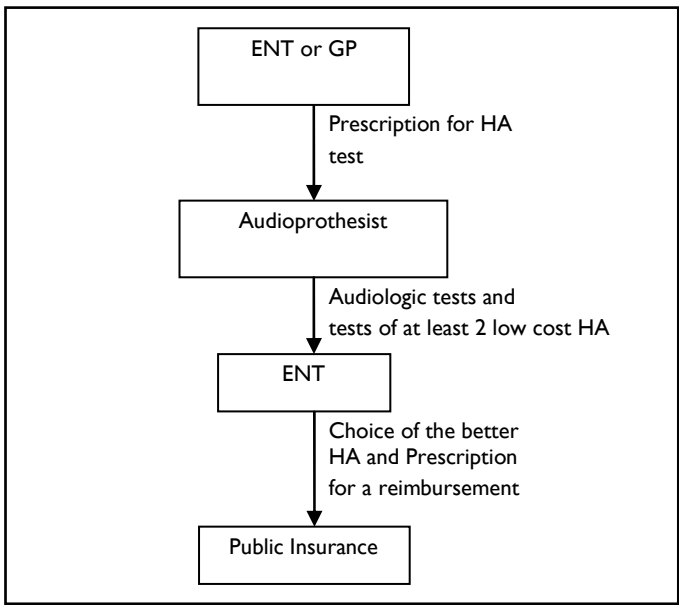
A 2006 consumer report by the "Stiftung Warentest",[122] states that manufacturers in Germany claim that "already" the majority of patients go through the "direktversorgung" scheme.

HA are totally reimbursed for children (up to the age of 18 years) and for adults, a lump sum of around €421 (Eur25: 403) for the HA and €35 (EUR25: 34) for the ear mould is reimbursed for one HA. This sum can vary slightly (± €10 - €20) according to the insurance of the patient and the area where he lives. In case of binaural hearing loss, a lump sum of around €337 (Eur25: 323) for the second HA is reimbursed. Dispensers receive €190 (Eur25: 182) for six years of HA maintenance.

For binaural fittings, only patients having a hearing loss of at least 30 dB in the best ear in only one frequency between 500 to 3000 Hz and having a speech discrimination score (SDS)[h] less than 80% at 65 dB in the best ear in a speech audiometry (with helmet) using one syllabic word are eligible for public help.

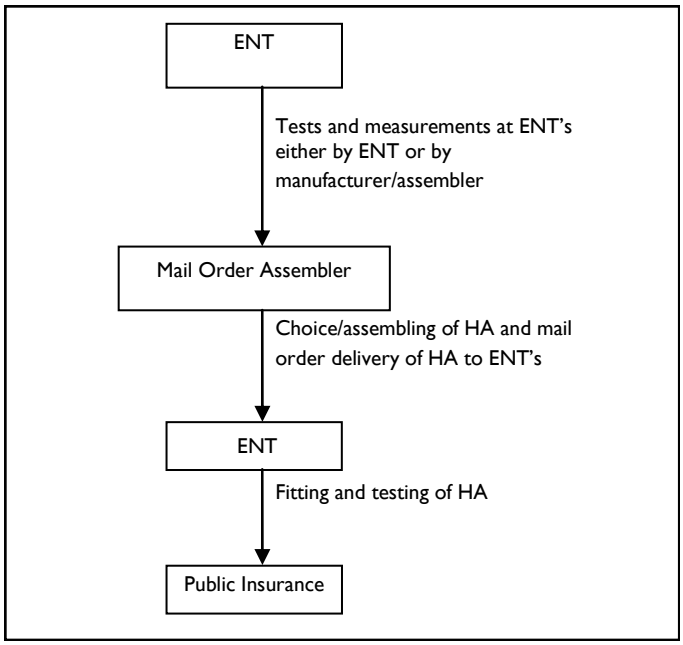
For monaural fittings, only patients having a hearing loss of at least 30 dB in 2000 Hz or in two frequencies between 500 to 3000 Hz are eligible. They have the right to have new HA every five years. In case of hearing loss changes, a renewal of HA is accepted if it gives at least 10% more speech discrimination in comparison with the old HA.

Figure 17: HA provision in Germany: "classical" scheme.



[h] The speech discrimination test analyzes the patient's ability to hear but also to identify words. The audiologist says a series of monosyllabic words at the same intensity level (easily detectable) and the patient must repeat the words. The speech discrimination score is the percentage of words correctly identified.

Figure 18: HA provision in Germany: "Direktversorgung" scheme.



6.2.4 The Netherlands

Two ways exists to obtain HA in the Netherlands. Firstly, patients go to the ENT with a referral by their GP (who acts as a gatekeeper) who administers audiologic tests. After this visit they go to a private audioprothesist who performs the HA fitting and advises the patients on HA use, and then they return to the ENT and obtain a prescription for a reimbursement. The second path is similar except that patients go to an audiologic centre[i] instead of an ENT.

A fixed lump sum of €650/HA is reimbursed for children (up to the age of 15 years) and €476/HA for adults (Eur25: 457). Ear moulds are fully reimbursed (about €50) every 20-30 months depending on the patient's health insurance.. Alternatively, the ENT may refer patients to an audiologic centre if the patient requires a more comprehensive diagnosis.

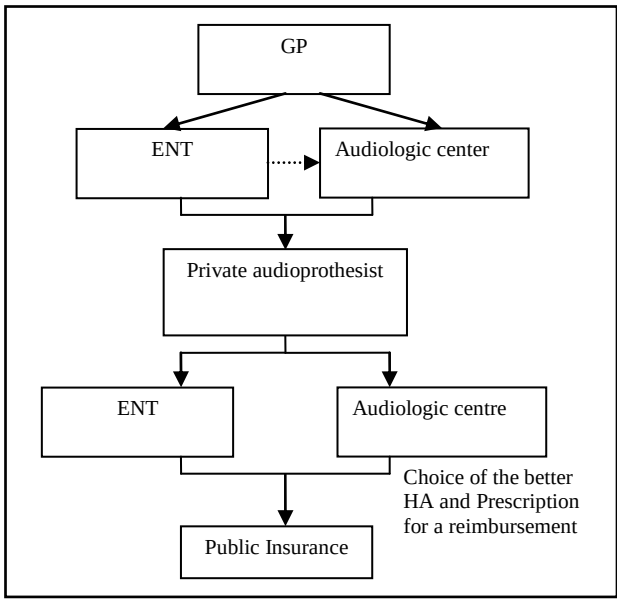
A hearing loss exceeding 35 dB in the best ear at 1000 Hz, 2000 Hz and 4000 Hz and a 20% increase of words understood in speech audiometry (55dB) with the HA are required to obtain a reimbursement. A prescription for two HA is given when speech enhancement is at least 10% with binaural fitting compared to monaural fitting and when a hearing recovering of 45° in the localization test is observed[j]. Patients have the right to renew HA every five years. After five years, €476/HA are again reimbursed. If patients wait six years before requesting a new HA, €566.50 will be reimbursed, and if they wait 7 years, €657.50 will be reimbursed.

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[i] an audiologic centre ("audiologisch centrum") is a regional multidisciplinary centre involving audioprothesists, psychologists, speech therapists, social workers, etc. dealing with speech-language related pathologies in a broad sense. A referral by a GP, ENT, paediatrician or psychiatrist is required for treatment at such a centre.

[j] In the localization test, a minimum of three loud-speakers are placed in the front of the patient. The aim of this test is to measure the capacity of people to localize a sound and is used mainly to assess the benefit of a binaural fitting compared to a monaural fitting.

Figure 19: HA provision in the Netherlands.



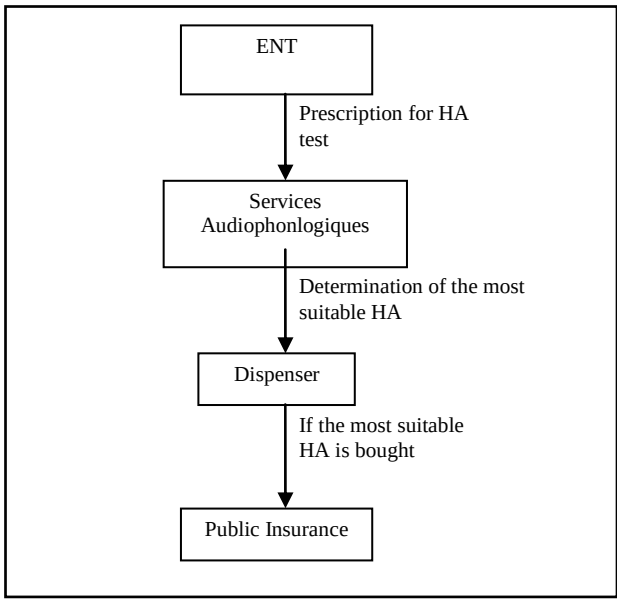
6.2.5 Luxembourg

Patients visit the ENT and receive a prescription for a HA test. After this, they go through a public organism called "Services Audiophonologiques" (SAP) which determines the most suitable HA for the patient based on tests performed at the SAP headquarters or in regional centres.[123] Then, the patients choose a dispenser to buy the prescribed HA.

If patients buy the prescribed HA, even abroad, the HA price is totally reimbursed. HA qualifying for reimbursement are listed with reference prices (which equal the maximum reimbursements) ranging from €384 to €1900 for monaurally fitted devices (rates applying on 01/01/2008).[123] Apparently, binaural fittings are reimbursed if the price of the second HA does not exceed 80% of the price of a monaural fitting, which corresponds to minimum and maximum prices of €332.1 and €1520 respectively as confirmed by published reference prices (rates applying on 01/01/2008). Adults have the right to obtain a new HA every five years and children (up to the age of 15 years), every three years. During these five years (three for the children), maintenance is reimbursed up to a maximum amount of 25% of the HA price.

It is the ENT who decides if HA fitting is needed. No specific condition on hearing loss degree is determined. Data from Luxemburg,[123] show 1715 fittings were performed in patients of all age categories in 2006, 1030 of them for first time HA users and and including 1259 stereophonic fittings. For comparison, in the same year there were 28 824 fittings for patients of all ages of which 17 606 bilateral fittings in Belgium. Going by a crude general population ratio (the number of residents for both countries differs by a factor 22) we observe that the hearing aid fitting rate is about 30% higher in Luxemburg.

Figure 20: HA provision in Luxembourg.



6.2.6 Switzerland

Hearing impaired people go to private hearing health care clinics where audiologic tests are performed free of charge. Then, they go to an ENT specialist who determines whether they need a simple, complex or very complex rehabilitation ("Erstexpertise"). Hearing aids are indeed classified in three levels according to their technological rehabilitation complexities. If reimbursement is allowed, the reimbursed amount will vary according to these three levels. The classification of patients in these categories is based mainly on audiometric tests, but also on socio-emotional factors as assessed through a structured patient questionnaire,[k] and on work-related status as assessed informally by the treating physician.[124] Moreover, other factors such as the presence of other disability (for example blindness) are also taken into account in the calculation.

For patients in "assurance-invalidité" (AI) age, the maximum amounts reimbursed will vary from Swiss franc 1570 (Eur25: 787), (broken down into 600 Swiss francs for the device and a lump sum of 970 Swiss francs for services offered by the audioprothesist) for a monaural fitting and a simple rehabilitation need, up to Swiss franc 4065 (Eur25: 2038) for a binaural fitting (respectively 2100 franc and 1965 franc for the device and services by the audioprothesist) and very complex rehabilitation needs. For patients in "assurance-vieillesse et survivants" (AVS) age, the amount reimbursed will vary from Swiss franc 1177.5 (Eur25: 590) (450 francs for the device and the remainder for services by the audioprothesist) for a monaural fitting and a simple rehabilitation need, to Swiss frank 1841.25 (Eur25: 923) (788 franc for the device and the remainder for services by the audioprothesist) for a monaural fitting and very complex rehabilitation needs. The separate maximum reimbursements for services by the audioprothesist include the ear mould.

Data for 2005,[125] indicate that 50% of all forms of rehabilitations (17 907 out of a total of 35 871) concerned monaural fittings for patients in the AI-scheme.

Concerning the reimbursement conditions, only patients having a hearing loss of at least 30 dB in two frequencies between 500 to 4000 Hz are eligible for public reimbursement. Moreover, a surgical treatment must be impossible or not desired by the patient, the patients' anatomy must allow the HA fitting, and the patient must be motivated to use a HA.

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[k] It was not established which specific questionnaire is used for this purpose. Moreover, it should be noted instruments such as the Hearing Handicap Inventory in part cover work-related issues.

After the fitting ("vergleichende anpassung") which should cover several devices and in principle one device requiring no patient co-payment,[125] an ENT (member of the "Fédération des médecins suisses d'Otorhinolaryngologie") will control if the HA is correctly adapted ("Schlussexpertise"). If it is not the case, the patient will go back to an audioprothesist.

To have a binaural fitting, conditions differ for patients in age of invalidity insurance (AI age) or for patients past retirement age (AVS age).

For patient in AI age, binaural fitting is reimbursed in the following conditions:

- A hearing loss difference between the two ears < 30% when measured by the "CPT-AMA" table (Table 22)
- A difference of the maximum word discrimination score between the two ears < 30% (quiet speech audiometry)
- A difference of speech intelligibility between the two ears < 40 dB (quiet speech audiometry)

For patients in AVS age, only monaural fittings are reimbursed, except if the patient had the right to have a binaural fitting before the age of retirement (in AI age).

Table 22: CPT/AMA table to calculate the hearing loss percent in tonal audiometry in quiet.

Hearing loss (in dB HL)	500 Hz	1000 Hz	2000 Hz	4000 Hz
10	0.2	0.3	0.4	0.1
15	0.5	0.9	1.3	0.3
20	1.1	2.1	2.9	0.9
25	1.8	3.6	4.9	1.7
30	2.6	5.4	7.3	2.7
35	3.7	7.7	9.8	3.8
40	4.9	10.2	12.9	5.0
45	6.3	13.0	17.3	6.4
50	7.9	15.7	22.4	8.0
55	9.6	19.0	25.7	9.7
60	11.3	21.5	28.0	11.2
65	12.8	23.5	30.2	12.5
70	13.8	25.5	32.2	13.5
75	14.6	27.2	34.0	14.2
80	14.8	28.8	35.8	14.6
85	14.9	29.8	37.5	14.8
90	15.0	29.9	39.2	14.9
95	15.0	30.0	40.0	15.0
100	15.0	30.0	40.0	15.0

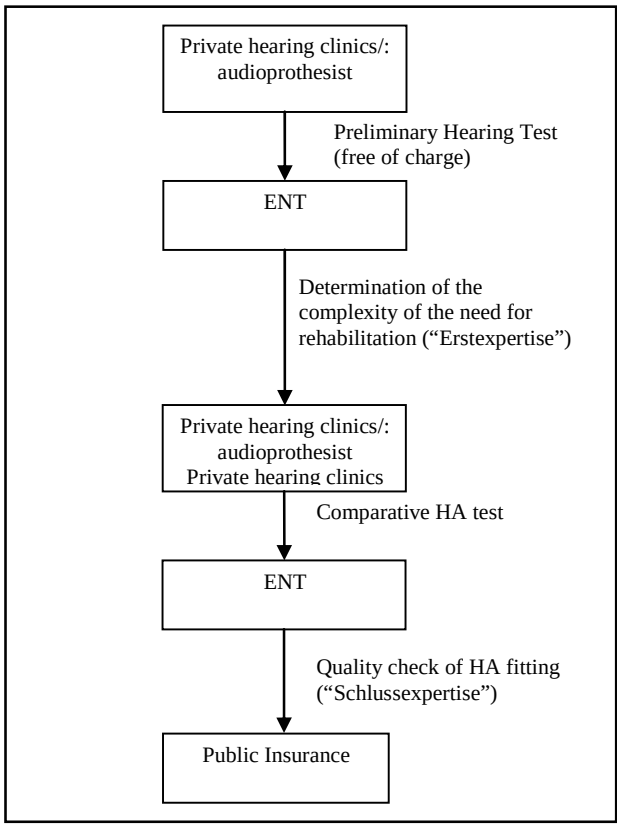
This table indicates the hearing loss percentage in tonal audiometry for each frequency. The percentage of hearing loss for each ear is calculated by the addition of the four values at 500, 1000, 2000 and 4000 Hz
CPT: Current Procedural Terminology
AMA: American Medical Association

The demand for a renewal of HA can be introduced every six years for patients in AI age and every five years for patient in AVS age. The reimbursement will be accorded only if the HA is not adapted any more to the patient (according to the ENT specialist). If the situation of the patient has changed (worsening of hearing loss, etc.), the ENT may justify to renew the HA before this date. But, before this date and if the situation of the patient has not changed, patients in AI age have to pay the total amount of a new HA the first two years, and 25%, 50% or 75% of the amount fixed according to the complexity of the rehabilitation, is reimbursed during the third, fourth or fifth year respectively.

However, they receive this partial reimbursement only if the new HA improves their hearing capacity. Patients in AVS age must respect a waiting period of five years.

A 2007 report by the "Eidgenössische Finanzkontrolle" (EFK), [125] a Swiss public body responsible for monitoring public finances, advocates the abolition of the patient three-level reimbursement scheme, which came into practice on April 1st 1999, as this scheme seems "expensive and not well founded". The scheme seems to entail an upward shift in the reported severity of patient cases (causing an increase of the budgetary stake of hearing aid expenses for the highest patient case category from 36% in 2001 to 50% in 2005). The report states there is no straightforward relation between patient case severities and necessary treatment costs. Therefore it is suggested to replace the current scheme by a uniform lump sum scheme, allowing for exceptions to be based on individual patient files. Additional recommendations made by the EFK include the reduction of reimbursement fees for services by audioprothesists and the need to examine the feasibility of public tendering for HA. Compared to Germany and Norway the report indicates that comparable hearing aids are in most comparisons more expensive in Switzerland. Furthermore it is estimated that hearing aid use is comparatively low in Switzerland (2.2% of the Swiss population versus 3.7% and 3-3.5% respectively in Norway and Germany). With around 57 000 HA delivered through public health care in 2005 Switzerland has fewer HA per resident (131 residents for one HA, 2005), in comparison with the figures quoted for Germany (117 residents per HA, 2004) and Norway (76 residents per HA, 2005). The rate for Belgium (2006) is estimated to be 224 residents for one HA. However, it should be stressed that the data for Germany probably also included devices that were not reimbursed, questioning the comparability of these data.

Figure 21: HA provision in Switzerland.



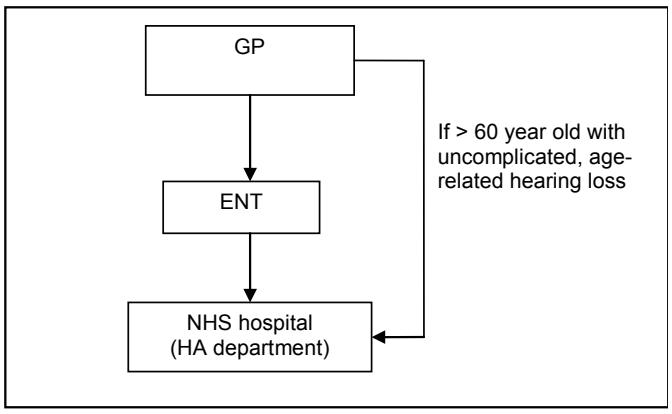
6.2.7 United Kingdom

In the United Kingdom, patients with hearing impairment are referred by the general practitioner to an ENT specialist who performs the audiologic tests. Then, they go to the hearing aids department of a National Health Service (NHS) hospital to obtain their HA. Patients aged 60 year and over and with uncomplicated age-related hearing loss can directly go to a NHS hospital without visiting the ENT specialist. Patients can also directly buy a HA with a private dispenser. No condition on hearing loss degree is determined.

In NHS hospitals, HA are issued free of charge. In principle, patients have their hearing aids on loan from the NHS and should return them to their local audiology departments in case of disuse or even during long-term stays outside the UK.[126] The fitting is usually monaural and patients can not choose their HA. Long waiting lists have been reported in the past (UK-wide average of 47 weeks in 2004).[117] Children up to the age of 18 years are usually given priority and are generally fitted bilateral HA. In the past, only analogue HA were delivered. Since 2001 digital HA are also provided. If patients want to choose their HA they have to go to a private dispenser and pay the entire HA price. Batteries, repairs and replacements are free of charge, avoiding damage through misuse.[126]

The NHS launches public tenders but negotiated HA prices are kept confidential.

Figure 22: HA provision in UK.

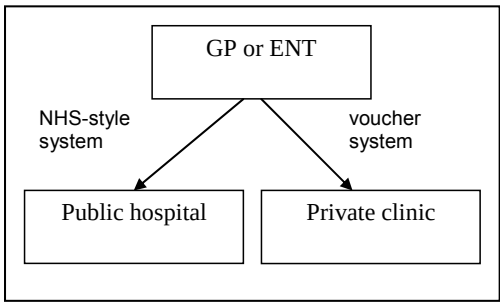


6.2.8 Denmark

Patients suffering "hard hearing impairment" are referred by their general practitioner or an ENT specialist to a public hospital. In this public hospital, the best and cheaper HA is fit free of charges. HA are warranted for a four-year period. From our research, we did not find if there were formal conditions on hearing loss degree to obtain a reimbursement nor how this "hard hearing impairment" was defined. However, one would assume that relatively easy criteria are applied as the expenses per head of population for hearing services are reportedly four times greater in Denmark than in the UK.[117]

If patients go to a private dispenser they can choose their preferred HA and a lump sum of around 5660 Danish kroner (Eur25: 546) is reimbursed through a voucher system if they have a certificate of severe hearing impairment delivered by a ENT specialist. For patients insured through the main health insurance company 'Danmark', an additional amount of 1000 Danish kroner (Eur25: 100) is reimbursed. In 2002 the state decided to subsidize purchases through private dispensers to reduce waiting lists in public hospitals, a policy measure which was followed by an increase in the number of private clinics from 40 to around 100, which are currently fitting some 35-40% of all hearing aids in Denmark.[127]

Figure 23: HA provision in Denmark.



6.2.9 Further international comparisons

Two publications,[117, 118] offer a general overview of internationally applying reimbursements for HA in adults. The main relevant elements quoted by these sources include:

- absence of public reimbursement for HA in adults (Spain and the majority of patients in Portugal)
- waiting lists for reimbursed HA lasting up to several years (Finland, Poland, Sweden)
- the use of an authorized product list for public reimbursement (Italy)

Arlinger 2006,[118] offers an overview of various international estimates of newly fitted hearing aids in 2004. As can be seen from Table 23 Belgium stands out as a country which has relatively few hearing aids fitted per head-of-population. A further remarkable finding is that the proportion bilateral fittings is very variable, but around 50% in most countries with a public health coverage of HA. The data reported for Belgium are consistent with our calculations (see this chapter and chapters 4 and 7). The author states that "almost all countries seem to lack reliable statistic – the figures presented are estimates made by experienced specialists in the field".

Table 23: International comparison (2004 estimates): HA per capita and proportion of bilateral fittings.

COUNTRY	NUMBER OF HEARING AIDS PER 1000 RESIDENTS (2004)	PROPORTION OF BILATERAL FITTINGS (2004)
Brazil	0,4	?
Poland	1,6	20%
Finland	3	5%-20%
Belgium	4	56%
France	6	?
Ontario, Canada	6	50%-60%
Netherlands	7,5	40%-60%
USA	7,5	82%
Germany	8,5	50%-60%
Sweden	9	42%
Norway	12	50%-70%
England	12	20%-80%
Australia	15	75%
Denmark	18	40%-50%

Source: Arlinger 2006 (18)

6.2.10 Summary of reimbursement tariffs and conditions

Reimbursement varies strongly between countries, with countries like Denmark[1], Luxemburg and the United Kingdom providing full reimbursements of HA and other countries like Spain and Portugal providing no public coverage for (most) adults. It should be emphasized that the former countries all limit the choice of publicly reimbursed hearing aids on offer through listing HA eligible for reimbursement, either by product recognition (Luxemburg) or through public tendering schemes (the UK, Denmark).

Among countries with HA lump sum reimbursement schemes (meant to reimburse both HA devices, ear moulds and services by the audioprothesists) Belgium reimburses a lump sum which is lower than the aggregate lump sums in Germany, slightly lower than the Netherlands and substantially higher than the current reimbursement in France. The Swiss reimbursement scheme is more generous, but, under Swiss regulation the reimbursement for HA devices and HA fitting services by audioprothesists are separate, with the latter amounting to well up to 60% of total reimbursements for fitted devices.

It should also be appreciated that formal conditions for the degree of hearing loss needed to obtain a reimbursement differ between various countries and comparisons are not straightforward to make; different tests (and test reference values) apply. The few comparable data in this regard nevertheless seem to indicate that Belgian residents resort relatively less to (publicly reimbursed) HA: 76 residents per HA in Norway (2005), 131 residents per reimbursed HA in Switzerland (2005) as compared to 161 in Luxemburg (2006) and 224 in Belgium (2006).It is difficult to assess to which extent this phenomenon is related to underlying differences in epidemiology, reimbursement conditions or patient preferences. International data for 2004 further corroborate this finding: among 12 compared OECD countries with public coverage of HA Belgium ranks 10th in terms of number of HA per capita. The proportion of bilateral fittings in Belgium, however, is relatively high.

Various regulations applying in some of the countries that we described might be of interest to Belgian policy makers, including:

- mandatory testing of several devices including devices that would not require patient co-payment (beyond the minimal established amount) (Germany and Switzerland)
- public tendering procedures as observed under NHS-style coverage schemes (UK and Denmark)
- split lump sum reimbursements separating reimbursement for the HA device from the reimbursement of the actual HA fitting, possible repairs and other services (Germany and Switzerland)
- HA choice and testing procedures to be performed by government officials (Luxembourg (SAP) and NHS-style schemes)
- direct mail order manufacturers/assemblers supplying directly at the ENT's practice (Germany)

[1] Outside of voucher system for private dispensers

Table 24: Reimbursement tariffs and conditions for each country.

Country	Reimbursement tariff (in Eur25)		Hearing Loss degree		Other Criteria
	Monaural	Binaural	Monaural	Binaural	
Belgium	472	933	• 40 dB at 1000 Hz 2000 Hz 4000 Hz • A gain of at least 5 dB for the speech index or a gain of 5% in speech intelligibility measured without noise	• 45 dB in the best ear at 1000 Hz 2000 Hz 4000 Hz (40 dB since July 08) • A supplementary gain of 5 dB for the speech index or a supplementary gain of 5% in speech intelligibility measured without noise compared to monaural fitting. • An improvement of the sound source localization with binaural fitting compared with monaural fitting • No noticeable asymmetry between the two ears (in speech intelligibility and in tonal audiometry: the difference in the hearing threshold level average for 1000 – 2000 – 4000 Hz must be of maximum 30dB)	For children (up to the age of 18 years), the lump sum reimbursed is around €825 **(Eur25: 804)** for monaural fitting and around €1,634 **(Eur25: 1,593)** for binaural fitting.

Country	Reimbursement tariff (in Eur25)		Hearing Loss degree		Other Criteria
	Monaural	Binaural	Monaural	Binaural	
France	123	123/HA	No condition on hearing loss degree		Prescription by the ENT + For children up to the age of 20 years : List of HA with characteristics related to hearing problems reimbursed from €900/HA to €1400/HA)
Germany	+/-403 + 34 (mould) +190* (services)	+/-403 (1st HA) +323 (2nd HA) +34/HA (mould) +190* (services)	For monaural fitting, a hearing loss of at least 30 dB in 2000 Hz or in two frequencies between 500 to 3000 Hz.	For binaural fitting : 30 dB in the best ear in only one frequency between 500 to 3000 Hz and with a speech discrimination score less than 80% at 65 dB in the best ear (speech audiometry with helmet using one syllabic words)	
The Netherlands	457 + 50 (mould**)	457/HA +50/HA (mould**)	35 dB in the best ear at 1000 Hz, 2000 Hz and 4000 Hz and 20% increase of words understood in speech audiometry (55dB) with the HA. Binaural fitting if the speech enhancement compared to monaural fitting is at least 10% and if hearing recovering is of 45° in the localization test.		
Luxemburg	100%	100%	No condition on hearing loss degree		Visit to the SAP (headquarters or regional centres which chooses the most suitable HA

*Dispensers receive an additional 190€ in Germany meant to reimburse six years of HA (maintenance) services

** Depending on the patient's health insurer a new mould is reimbursed every 20/30 months

Country	Reimbursement tariff (in Eur25)		Hearing Loss degree		Other Criteria
	Monaural	Binaural	Monaural	Binaural	
Switzerland	590-2,038*		30 dB in two frequencies between 500 to 4000 Hz. For patient in AI age, binaural fitting is reimbursed in the following conditions: 1) A hearing loss difference between the two ears < 30% when measured by the "CPT-AMA" table (Table 22) 2) A difference of the maximum word discrimination score between the two ears < 30% (quiet speech audiometry) 3) A difference of speech intelligibility between the two ears < 40 dB (quiet speech audiometry)		socio-emotional factors and work-related status
United Kingdom	100%	(100%)**	No condition on hearing loss degree		Visit to a public hospital + HA list
Denmark	100%	100%	No condition on hearing loss degree was found		Visit to a public hospital (list of HA)***

* For patients in AI age : Eur25: 787 for a monaural fitting and a simple rehabilitation need to Eur25: 2,038 for binaural fitting and very complex rehabilitation needs. For patients in AVS age : Eur25: 590 for a monaural fitting and a simple rehabilitation need to Eur25: 923 for monaural fitting and very complex rehabilitation needs. It should be stressed maximum tariffs include separate maximum tariffs for hearing devices: 300€ - 526€ for AI and 225€ - 370€ for AVS

**The fitting is usually monaural (except for children)

***They can also visit a private dispenser and choose they HA. In this case, a lump sum of 546 is reimbursed if they have a certificate of hard hearing impairment delivered by a ENT specialist

6.3 HEARING AID PRICE COMPARISON

6.3.1 Methodological pitfalls

Comparing HA prices among countries is difficult for several reasons:

- HA prices were hard to obtain: in some countries such as Spain or Italy, neither manufacturers nor dispensers would provide us with HA prices, not even rough estimates. This can be explained by the fact that each dispenser negotiates prices with the manufacturer. As a result, they prefer to keep prices confidential to avoid comparison. In the UK, HA prices from private dispensers (for purchasing HA outside of the NHS) were available but the price at which NHS buys HA from manufacturers was confidential.
- In most countries HA prices vary strongly among dispensers. Because of negotiations prices provided by a dispenser were not representative of prices in the country. Because it is not possible to obtain prices of each dispenser for each country, results of this analysis have to be used with caution.
- What is included in the HA price can differ strongly from one dispenser to another. The ear mould, the fitting, the type of warranty, the period of the warranty, the maintenance and the period of the maintenance have all an impact on the HA price. A lower price could thus be explained by a lower warranty and so one. Because it was not possible to decompose the price for each element included, prices given by the dispenser have to be interpreted with caution.

6.3.2 Results and discussion

6.3.2.1 General Observations

Table 25 and Table 26 show prices by country for selected HA. Some prices are missing. This does not necessarily mean that the HA was not sold in the country, but rather that no information was obtained.

These prices must be interpreted with utmost caution for reasons explained in 6.3.1. However, analysis of the tables seems to highlight that there is strong variation between prices across countries. The average coefficient of variation (standard deviation divided by mean) for compared products across the country sample is 21% and the average factor separating lowest from highest prices is around 1,8[m].

6.3.2.2 Interaction between price levels and public policy

For low cost devices, data were too scarce to make meaningful price comparisons and to validate or invalidate the hypothesis that lump sum fees would lead to price alignment in this product segment.

One might, however, diffidently assume that HA prices are remarkably variable for such a standardized (and mostly imported) product, which raises the question as to which extent prices are influenced by policy-related factors rather than free market mechanisms. Prices for the UK and Denmark appear to be remarkably lower overall, which might be associated with the downward effect on prices public tendering procedures may exert.

m Seperately reported prices for HA, repairs and ear moulds were added together for Luxemburg.

Table 25: HA price comparison among countries (Belgium, France, Netherlands, Germany and Luxembourg).

Hearing aids (BTE)	BE	FR	NL	DE	LU
	HA price + ear mould + fitting + warranty (5 years)	HA price + fitting + warranty (2 years)	HA price + ear mould + fitting (repairs and maintenance not included)	HA price + fitting + warranty + maintenance (additional cost for ear mould: 72)	HA price-ear mould-repair
Siemens Lotus 13P	487				
Siemens Cielo directionnel	1414		929	1302	
Siemens Acuris Life	1706		1390	1781	1585-0-396*
Widex Senso Vita SV9 vc	1414		1006	1656	
Widex Bravissimo BV9 vc	1024	843	829		735-34-184*
Oticon Swift 70+	487	645	613	613	
Oticon Tego	1243	924	815	1044	
Lapperre 1400	1267				
Phonak Maxx 211 D	1267	803	816		
Phonak Savia art 211	2193	1876	1762	2355	1585-34-396*
Gn ReSound Canta 270	487				
Gn ReSound Discover V	951			766	
Gn resound +5	1438	1333			

BE = Belgium, FR = France, NL = the Netherlands, DE = Germany, LU = Luxembourg

* First number = HA price, second number = ear mould price, and third number = repair price

Table 26: HA price comparison among countries (Belgium, Denmark, Switzerland and UK).

Hearing aids (BTE)	BE	DK	CH	UK
	HA price + ear mould + fitting + warranty (5 years)	HA price + ear mould + fitting + warranty (4 years) + maintenance (4 years)	HA price + ear mould + fitting + warranty (1 years) + maintenance (1 years)	HA price + fitting + warranty (private dispenser)
Siemens Lotus 13P	487			
Siemens Cielo directionnel	1414	660	1098	1183
Siemens Acuris Life	1706	991	1643	
Widex Senso Vita SV9 vc	1414	876		
Widex Bravissimo BV9 vc	1024	564	1050	
Oticon Swift 70+	487			
Oticon Tego	1243	612	1123	1052
Lapperre 1400	1267			
Phonak Maxx 211 D	1267	564	847	855
Phonak Savia art 211	2193	1220	1963	1841
Gn ReSound Canta 270	487	564		
Gn ReSound Discover V	951	564		
Gn resound +5	1438	691	1010	1052

BE = Belgium, CH = Switzerland, DK = Denmark, UK = United Kingdom, US = United States

Key points

- **Compared to other countries with lump sum reimbursement, the Belgian lump sum for hearing aids is lower than in Germany, similar to the Netherlands and higher than in France. Overall reimbursement levels applying in Switzerland are higher.**
- **Comparisons of reimbursement criteria are difficult because the formal requirements are based on different tests.**
- **Compared to other western countries, the number of hearing aids provided per capita is low in Belgium, but the proportion bilateral fittings is relatively high.**
- **There appears to be a remarkable variation of hearing aids prices across European countries with Belgian prices being relatively high compared to other European countries. However, in an international comparison of hearing aid prices methodological pitfalls include confidentiality of key data, variation between dispensers and the inclusion of different cost items in published prices.**
- **Lower lump sums amounts or public tendering schemes appear to be associated with lower HA prices in those countries.**

7 CURRENT BUDGET AND EXPLORATIONS FOR THE FUTURE

7.1 RATIONALE AND SCOPE

Current reimbursement patterns will be analyzed from the Belgian healthcare payer's perspective to highlight observations of interest to policy makers. Moreover, given the strong impact of demographics on the prevalence of hearing impairment as described in chapter 1, the related future budget impact will be explored. Finally, the international comparability and adaptability of Belgian reimbursement criteria will be discussed.

The scope of this analysis is limited to non-implanted hearing aids in the adult Belgian population as reimbursed by the third party payer RIZIV/INAMI. Information on reimbursement criteria can be found in chapter 6.

7.2 METHODS AND SOURCES

RIZIV/INAMI data for reimbursements under the so-called "article 31" of the Belgian healthcare regulation,[128] were applied in both the description of the recent budgetary evolution and the exploration of future budgetary trends. Aggregated data per distinct billing code were available for the period 1995-2006 (by year of delivery). Detailed data by geographic region, patient birth year and sex were available for the year 2006. It should be noted that the RIZIV/INAMI billing data do not allow for a distinction between devices supplied to respectively first-time or repeat (experienced) users, which renders impossible any estimate of the proportion repeat prescriptions represent in the available data. A full description of all involved billing codes can be found in the appendix to this chapter.

Demographic data on Belgian residents from the Belgian Ministry of Economics (National Institute of Statistics NIS/INS) for 2006,[129] 2010, 2020 and 2030[130] were used in the geographic analysis and budgetary explorations.

Data on the number of HA shops per province for the three major distribution chains operating in Belgium were obtained through contacts with the companies involved.

A literature search was performed to identify publications on audiometric reference values for general (unscreened) populations that allow for comparison with current Belgian reimbursement criteria. Bibliographic sources and search criteria are described in the appendix to this chapter. Scrutiny of abstracts from 88 publications led to a final selection of 2 Scandinavian studies[19, 131] meeting the following criteria: prospective research in a general, i.e. randomly selected, population covering a wide adult age range, reporting hearing loss in terms of decibel hearing thresholds including measurements over the 1, 2 and 4 KHz frequencies. These criteria were applied in keeping with current Belgian reimbursement conditions. Budgetary explorations were modelled exclusively using the findings from the Norwegian study,[19] because its sample size was considerably larger than in the Swedish study (n=50 723 compared to n = 590) In the Norwegian study, population percentile values of hearing thresholds over frequencies 500-1000-2000-3000-4000-6000-8000 Hz in patients aged 20-89 were published as the arithmetic mean per patient of left and right ear measurements.

Audiometric values of relevance to the Belgian context as well as an example of how simulated population sizes are estimated are included in the appendix to this chapter.

7.3 RESULTS

7.3.1 Recent budgetary evolution

7.3.1.1 Main billing codes

Table 27 applies to devices reimbursed under Article 31 and delivered in 2006. The global budget for health care related to non-implanted hearing aids represented around €20 million in 2006 which corresponds to 0.1% of the overall budget for health care reimbursement that year. Two billing codes, respectively referring to bilateral hearing aid fittings in adults and unilateral hearing aid fittings in adults made up 95% of that amount.

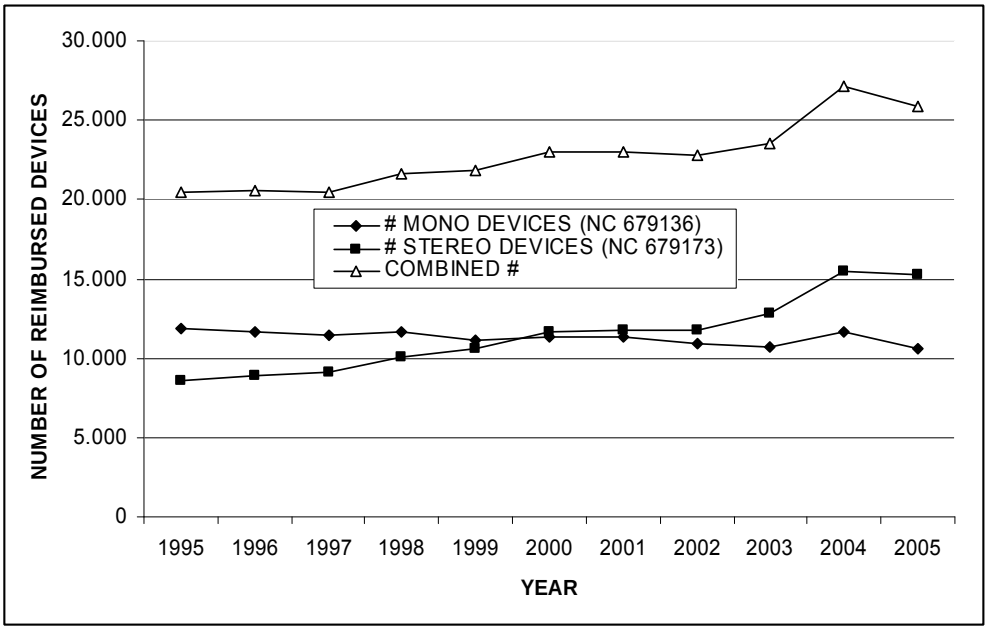
Table 27: Expenses for hearing aid reimbursements (2006).

NOMENCLATURE BILLING CODE		EXPENSES		#CASES	EXP/CASE
679173	Bilateral hearing aid fittings for Patients aged 18 and older	14.566.628 €	72%	15.726	926 €
679136	Unilateral hearing aid fittings for Patients aged 18 and older	4.719.154 €	23%	10.084	468 €
679195	Bilateral hearing aid fittings for Patients younger than 18	312.497 €	2%	198	1.578 €
OTHER (11 Distinct Billing Codes)		671.761 €	3%		
SUM		20.270.040 €	100%	NA	

Source: RIZIV/INAMI billing codes

Figure 24 depicts the evolution of the number of reimbursed unilateral and bilateral hearing aid fittings in adult Belgian residents by year of delivery for the period 1995-2005. Accounting for 2 HA per bilateral fitting a total of around 40 000 HA were delivered in 2005 through public reimbursement in the adult population of Belgian residents. An overall increase can be observed, mainly due to a marked rise in the use of bilateral hearing aid fittings.

Figure 24: Budgetary evolution (1995-2005) for two main billing codes.

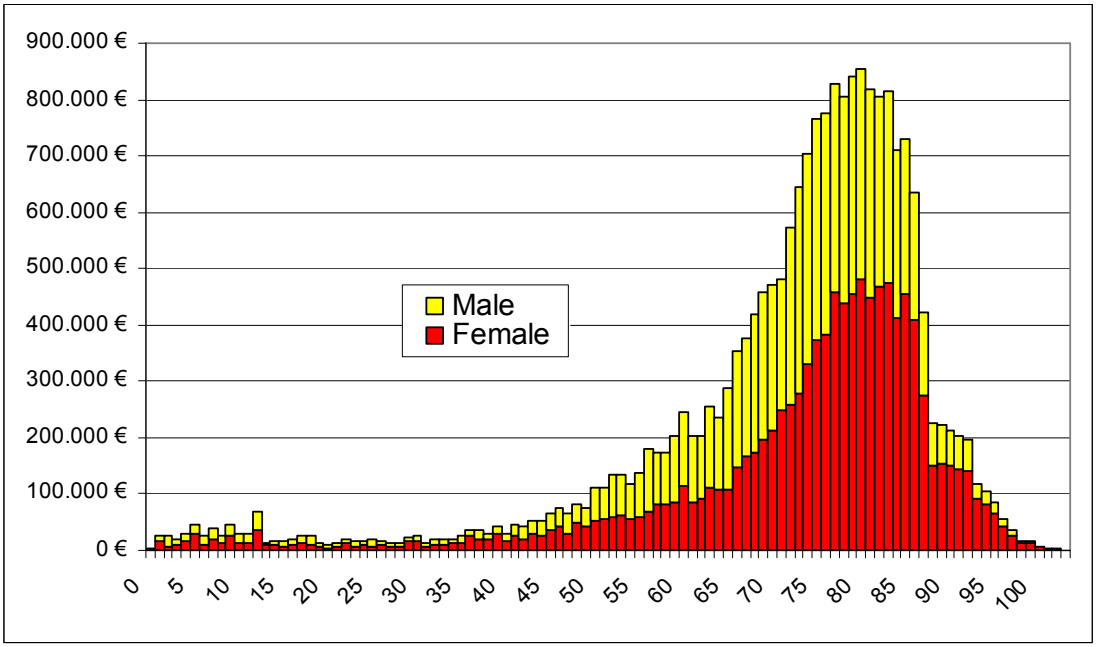


Source: RIZIV/INAMI billing codes

7.3.1.2 Demographic characteristics

Figure 25 gives an overview of all reimbursed expenses (article 31) for 2006 broken down by year of birth and gender. Patients between the ages of 60 and 90, incur 80% of all expenses. Women account for 53% of all expenses as indicated by the darker shaded part of the histogram, even while women have a lower age-specific prevalence of hearing loss than men (see chapter 1). Part of the explanation for this is obviously related to a better survival. Reimbursement of hearing aids in women is indeed more concentrated at older ages than in men. However, this is only a partial explication for the relatively large proportion of women who receive reimbursement for hearing aids, as will be shown in the explorations of demographic trends (7.3.2).

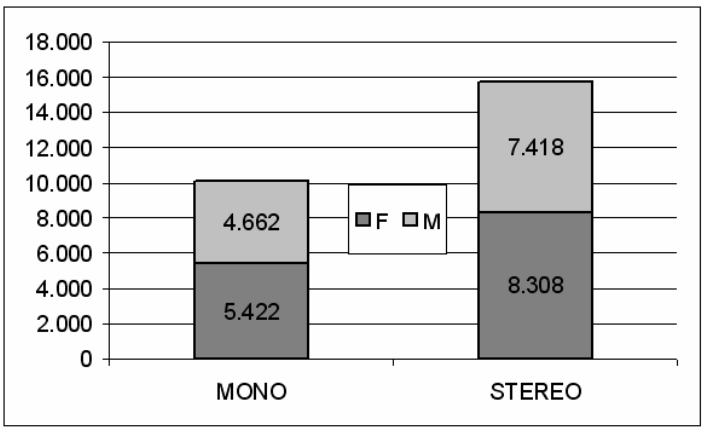
Figure 25: 2006 Expenditures by age and gender (genders stacked).



Source: RIZIV/INAMI billing codes

As shown in Figure 26, bilateral hearing aid fittings made up 61% of fittings in 2006. Both for unilateral and bilateral hearing aid fittings women account for around 53% of all devices.

Figure 26: Number of unilateral ("mono") and bilateral ("stereo") fittings in adults (2006), by age and gender (genders stacked).



Source: RIZIV/INAMI billing codes

7.3.1.3 Geographic utilisation patterns

Geographic patterns in reimbursed hearing aids are analyzed on the following pages. Figure 27 to Figure 30 concern consumption data directly standardized by age (groups of 5 years from the age of 20 onwards) and gender.

The ratio value "100" refers to the average observed value in the global Belgian population whereas the ratio values per region indicate the overall consumption if the regional consumption profiles by age and gender categories would be extrapolated to the Belgian population.

Respectively the figures show:

- Figure 27 and Figure 28: the number of bilateral hearing aid fittings in the adult population (billing code 679173)
- Figure 29 and Figure 30: the number of unilateral hearing aid fittings in the adult population (billing code 679136).

Table 28 gives an overview of the most important observations emerging from these geographic analyses. The overall variance in consumption patterns seems to be less pronounced for unilateral hearing aid fittings (coefficient of variation = 9%) as opposed to bilateral hearing aid fittings (coefficient of variation = 13%).

Table 28: Overview Information from geographic analyses.

VARIABLE	VALUE FOR RATIO = 100	MEDIAN	MINIMUM	MAXIMUM	MEAN	STANDARD DEVIATION	FIG
Reimbursed Bilateral hearing aid fittings	15.639 fittings	Antwerp (107)	Flemish Brabant (86)	Limburg (125)	103	13	4-5
Reimbursed Unilateral hearing aid fittings	10.045 fittings	East Flanders (97)	Limburg (88)	Flemish Brabant (115)	98	9	6-7

Also plotted on the charts (Figure 28 and Figure 30) are the numbers of shops per 100 000 capita per province as derived from Table 29, which does not allow for any clear-cut observations. This could be explained by the fact that these data do not take the actual size of various shops into account. Neither do they list shops that are not affiliated to one of the three major distribution chains.

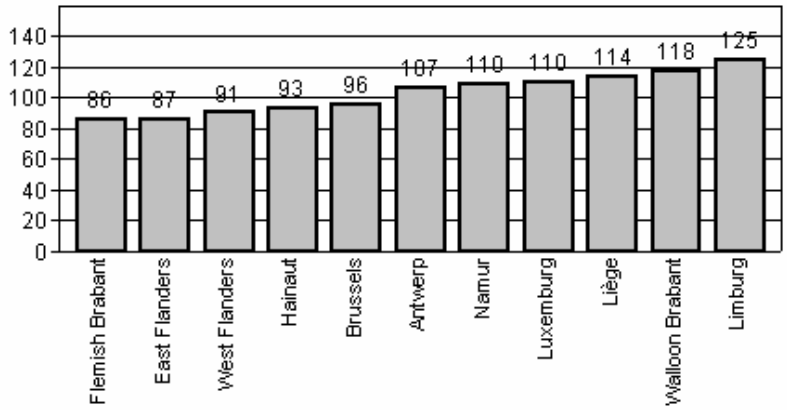
Table 29: Number of retail points per Belgian province.

Province	Distribution Chain			Total
	Veranneman	Lapperre	Dialogue	
East Flanders	38	39	25	102
Antwerp	33	26	18	77
Hainaut	39	27	11	77
Flemish Brabant	34	23	13	70
West Flanders	19	30	10	59
Liège	16	21	13	50
Limburg	6	21	15	42
Luxembourg	24	8	1	33
Walloon Brabant	19	9	0	28
Namur	10	10	4	24
Brussels	1	3	4	8

Source: 2007 data obtained from retail chains

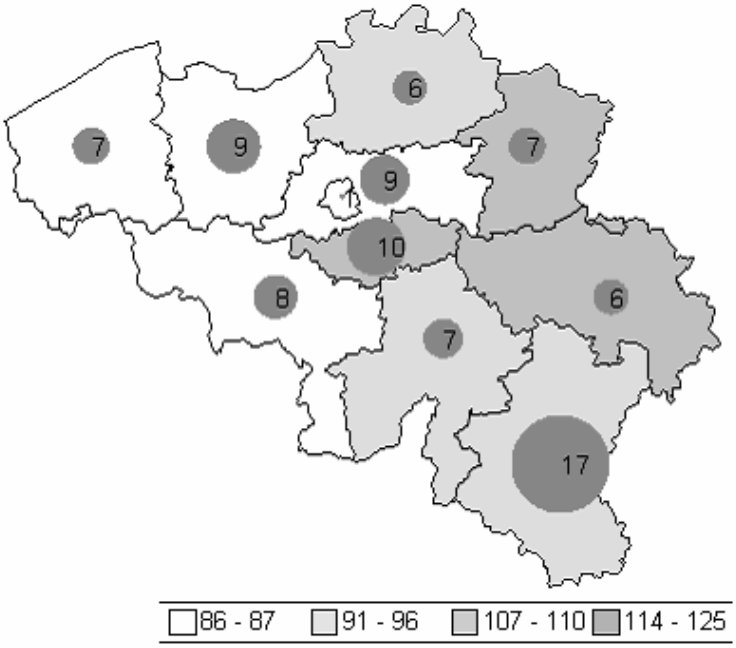
As can be derived from the mapped data the most striking conclusion is that there seems to be an East West divide as regard the relative use of device types whereby the occurrence of unilateral and bilateral hearing aid fittings is more pronounced in respectively the Western and Eastern part of Belgium. Given the higher average reimbursement per bilateral hearing aid fitting (€926) compared to unilateral hearing aid fittings (€468), it should be expected that overall public reimbursement expenses for hearing aids show the same east-west divide.

Figure 27: Ratios by province, number of reimbursed bilateral hearing aid fittings (2006).



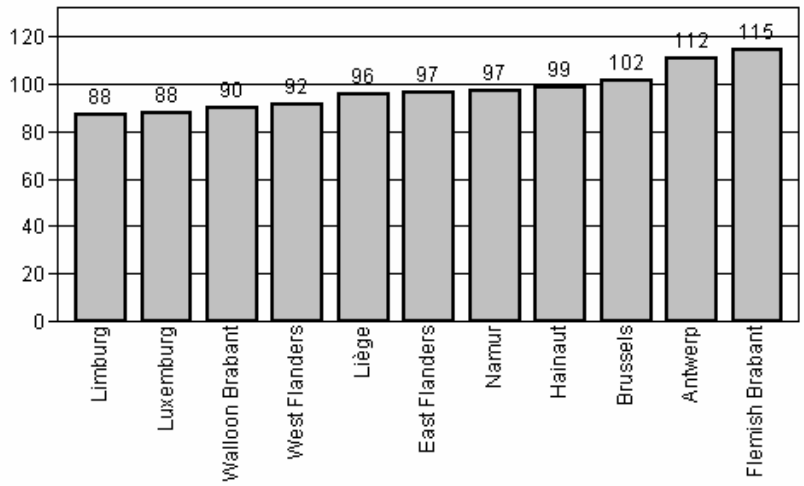
Source: RIZIV/INAMI Statistics (budgetary data) and Ministry of Economics (population data)

Figure 28: Ratios by province (number of reimbursed bilateral hearing aid fittings 2006) and number of shops per 100 000 capita.



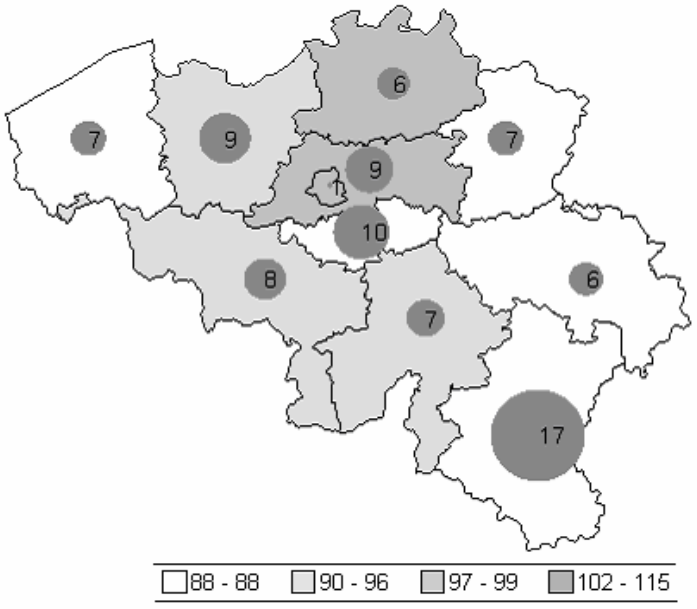
Source: RIZIV/INAMI billing codes (budgetary data) and Ministry of Economics (population data) and data collected by project researchers (shops per province)

Figure 29: Ratios by province, number of reimbursed unilateral hearing aid fittings (2006).



Source: RIZIV/INAMI Statistics (budgetary data) and Ministry of Economics (population data)

Figure 30: Ratios by province (number of reimbursed unilateral hearing aid fittings 2006) and number of shops per 100 000 capita.



Source: RIZIV/INAMI billing codes (budgetary data) and Ministry of Economics (population data) and data collected by project researchers (shops per province)

7.3.2 Exploration of demographic trends

By taking the Belgian demographic scenarios for 2010, 2020 and 2030 as estimated by the Belgian National Institute of Statistics[130] and applying the percentile-based reference values from the Norwegian hearing impairment study[19] we can derive present and future patient populations meeting the current reimbursement criteria for Belgium. Table 30 gives an overview of the numbers involved. It should be stressed that these numbers concern simulations based solely on audiometric criteria in terms of average decibel hearing losses as they are currently established. As additional criteria for reimbursement apply in Belgium, these numbers are likely to overestimate true population sizes of patients receiving public reimbursement. Related methodological points of attention are discussed in the section on "main limitations and hypotheses".

According to this analysis the number of patients potentially eligible for reimbursment of hearing aids between the ages of 20 and 89 is slightly above 700 000 in 2006, with women making out only 43% of the concerned population, a considerable difference with the proportion in the overall budget women currently hold. The overall number is set to rise over 1 000 000 in 2030. Among these patients around 50% qualify for bilateral hearing aid fittings, a percentage remaining more or less stable over the studied period.

Table 30: Patient populations for 2006 – 2010 – 2020 – 2030.

	PATIENT POPULATION BY YEAR AND TYPE OF FITTING							
	2006		2010		2020		2030	
AGE - SEX	UNILAT	BILAT	UNILAT	BILAT	UNILAT	BILAT	UNILAT	BILAT
60 - 69 F	51.695	0	57.881	0	69.406	0	71.432	0
60 - 69 M	119.803	45.621	137.947	52.530	167.133	63.644	174.912	66.606
70 - 79 F	121.598	46.305	117.193	44.627	129.522	49.322	157.811	60.094
70 - 79 M	184.474	87.809	182.900	87.060	219.274	104.374	274.792	130.801
80 - 89 F	131.407	125.099	153.139	145.788	155.489	148.025	185.528	176.623
80 - 89 M	104.175	66.116	121.870	77.347	136.193	86.437	181.217	115.013
SUM	713.152	370.951	770.929	407.352	877.015	451.802	1.045.691	549.137

Source: RIZIV/INAMI billing codes (budgetary data) and Ministry of Economics (population data) and Norwegian study (derived prevalence rates)

By comparing the stakes various patient groups hold in respectively the simulated overall population and the actual budgetary expenses for 2006 in Table 31 we can conclude that Belgian women incur relatively higher expenses compared to Belgian men than would be expected from the epidemiology of hearing loss and demography.

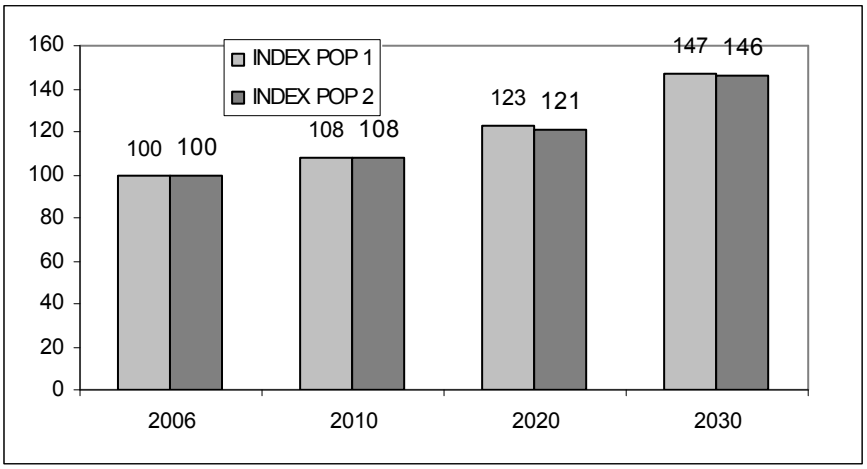
Table 31: Demographic and budgetary stakes for various patient categories.

AGE/SEX	2006 (actual) EXPENSES		2006 PATIENT POPULATION		EXP/POP
60 - 69 F	1.385.006 €	8%	51.695	7%	1,1
60 - 69 M	1.849.078 €	11%	119.803	17%	0,6
70 - 79 F	3.712.286 €	21%	121.598	17%	1,3
70 - 79 M	3.681.301 €	21%	184.474	26%	0,8
80 - 89 F	4.054.663 €	23%	131.407	18%	1,3
80 - 89 M	2.719.591 €	16%	104.175	15%	1,1
SUM	17.401.925 €	100%	713.152	100%	1,0

Source: RIZIV/INAMI billing codes (budgetary data) and Ministry of Economics (population data) and Norwegian study (derived prevalence rates)

In correcting the set increase in the patient population eligible for hearing aid reimbursements by the age and gender specific proportion of actual budgetary expenses, we can derive an estimate for the RIZIV/INAMI hearing aid budget for patients aged 20-89. Figure 31 depicts respectively the change in patient population size ('POP 1') and the resulting budgetary change ('POP 2') taking 2006 as a base year. Based on these figures we conclude that, only through the demographic evoluation, 'ceteris paribus', the corresponding budget is set to increase with 46% between 2006 and 2030, implying an average annual exponential (real) growth rate of 1,6%.

Figure 31: Evolution of patient populations ('POP 1') and budget driven by demographics ('POP 2').



Source: RIZIV/INAMI billing codes (budgetary data) and Ministry of Economics (population data) and Norwegian study (derived prevalence rates)

It should of course be noted that the above projections concern static extrapolations of observed 2006 consumption patterns. Dynamic effects could exert a significant influence on the final budgetary outcomes. If for instance the stake bilateral hearing aid fittings hold would have risen from 61% in 2006 to 80% or 100% in 2030, the final budgetary increase would surpass the projected one by a factor of respectively 1,1 and 1,2 following the relative average reimbursement for stereophonic (926€) versus monophonic (468€) hearing aids in 2006. This simulation obviously also assumes that reimbursement rules do not change in the meantime.

7.3.3 Further explorations

7.3.3.1 International comparisons

The comparison of various foreign reimbursement schemes in chapter 6 did not yield comparable outcomes as audiometric criteria on decibel hearing loss were coupled with various additional (and restrictive) criteria, implying different patient populations.

However, the German reimbursement conditions for unilateral hearing aid fittings are easier to compare and can be implemented in our model. In Germay, patients having a hearing loss of at least 30 dB in 2000 Hz or in two frequencies between 500 to 3000 Hz are eligible for reimbursement. When applying these criteria to our simulation model we find that the corresponding Belgian population (2006 population) would increase from slightly above 710 000 (see Table 30 and Table 32) to almost 970 000 (see table Table 32) Belgian residents qualifying for reimbursement (or a 36% increase of our baseline estimate).

However, the corresponding Belgian criteria for unilateral hearing aid fittings also include, other than the requirement of an average hearing loss of at least 40 dB at 1000 Hz, 2000 Hz and 4000 Hz additional measurements such as speech index scores. It should be concluded then that German reimbursement criteria for unilateral hearing aid fittings are more lenient than current Belgian ones to the extent that at least 36% more patients would qualify for reimbursement were German criteria to apply in Belgian public care. As illustrated in Table 32 the differences in reimbursement criteria also imply differences in relative proportions held by gender and age profile: the German scheme seems relatively more 'generous' for women and people below the age of 60.

Table 32: Modelled populations of Belgian residents qualifying for unilateral HA reimbursement under Belgian ("BE") and German ("GE") criteria.

AGE	SEX	BE CRITERIA	GE CRITERIA
50 – 59	M	0	69.499
60 – 69	F	51.695	51.695
60 – 69	M	119.803	119.803
70 – 79	F	121.598	243.196
70 – 79	M	184.474	184.474
80 – 89	F	131.407	197.111
80 – 89	M	104.175	104.175
SUM		713.152	969.952
% WOMEN		43%	51%
% PATIENTS < 60 years		0%	7%

Source: RIZIV/INAMI billing codes (budgetary data) and Ministry of Economics (population data) and Norwegian study (derived prevalence rates)

The main merit of this analysis lies in the illustration that international comparisons of insurance schemes based on audiometric values are not straightforward in design given the multitude of variables involved. In the one comparison we were able to make (with the German healthcare insurance scheme) we found Belgian reimbursement criteria to be rather restrictive.

7.3.3.2 Alternative reimbursement criteria

As a further exploration we apply various minimal average thresholds to assess the corresponding populations eligible for (unilaterally fitted) devices in Belgium (Table 33). We observe a wide margin in population sizes: respectively 69% more and 93% less eligible patients compared to the current situation for averages of 30 and 50 dBHTL. Moreover, the stake women hold in various modelled populations fluctuates widely and is maximal under the currently applying regulation.

Table 33: Sensitivity of 2006 patient populations (Belgian residents) to specific minimal average thresholds.

		MINIMAL AVERAGE dBHTL AT 1,2,4 KHz				
AGE	**SEX**	**30**	**35**	**40**	**45**	**50**
50 – 59	**M**	69.499	69.499	0	0	0
60 – 69	**F**	51.695	51.695	51.695	0	0
60 – 69	**M**	239.607	239.607	119.803	119.803	0
70 – 79	**F**	243.196	121.598	121.598	121.598	0
70 – 79	**M**	276.710	276.710	184.474	184.474	36.895
80 – 89	**F**	197.111	197.111	131.407	131.407	0
80 – 89	**M**	125.010	125.010	104.175	104.175	13.890
SUM		1.202.827	1.081.229	713.152	661.457	50.785
INDEX		169	152	100	93	7
% FEMALES		41%	34%	43%	38%	0%

Source: RIZIV/INAMI billing codes (budgetary data) and Ministry of Economics (population data) and Norwegian study (derived prevalence rates)

As a final analysis we examine modelled populations by various frequency sets. Table 34 summarizes some of these scenarios. In keeping with expected stages of presbycusis we modelled hearing loss (as defined by an average loss of at least 40 decibel) over various frequency sets:

- 4000-6000-8000 Hz: frequencies involved in first stage of presbycusis: "Scenario 1"
- 2000-4000-6000-8000 Hz: intermediate stage of presbycusis: "Scenario 2"
- 1000-2000-4000-6000-8000: final stage of presbycusis: "Scenario 3"

It can be concluded that overall population sizes vary considerably dependent on the frequency sets that are accounted for in averaged hearing loss rates. In our simulated scenarios the stake held by women is reasonably stable whereas the proportion of people below 60 years varies considerably.

Table 34: Sensitivity of 2006 patient populations (Belgian residents) to tested frequencies.

AGE	SEX	SCENARIO 1	SCENARIO 2	SCENARIO 3
40 – 49	M	80.774	80.774	0
50 – 59	F	69.411	0	0
50 – 59	M	173.747	173.747	69.499
60 – 69	F	129.237	129.237	51.695
60 – 69	M	239.607	239.607	239.607
70 – 79	F	243.196	243.196	243.196
70 – 79	M	332.052	276.710	276.710
80 – 89	F	236.533	236.533	197.111
80 – 89	M	125.010	125.010	125.010
SUM		1.629.566	1.504.813	1.202.827
% WOMEN		42%	40%	41%
% PATIENTS < 60 years		20%	17%	6%

Source: RIZIV/INAMI Billing Codes (budgetary data) and Ministry of Economics (population data) and Norwegian Study (Derived Prevalence Rates)

7.4 VALIDATION AND DISCUSSION OF FINDINGS

7.4.1 Main limitations and hypotheses

The findings from the preceding analyses should be read with a proper understanding of their main limitations, which are the result of the suboptimal character of available data:

- The historic budgetary data for the Belgian third party payer RIZIV/INAMI do not allow to separate first time and repeat hearing aid users, possibly confounding some conclusions based on time series analyses.
- More detailed epidemiological information for various Belgian regions would be desirable to correct for/elucidate the apparent east-west divergence in utilisation patterns.
- The analysis based on the Norwegian sample inevitably starts from the assumption that the findings for the Norwegian sample are valid for the Belgian population aged 20-89. The Norwegian authors themselves, however, stress that "there is also a need for national databases since the genetic and environmental factors may differ between countries." To illustrate this consideration there are the findings in chapter 6 that indicate that the number of inhabitants per delivered hearing aid is remarkably lower in Norway than in Belgium.

- The comparative analyses, both longitudinally and across healthcare systems are based on the Norwegian audiometric reference values. These values concern population percentiles at distinct testing frequencies. No prospectively collected prevalence rates, however, are given for per patient measurements (e.g. average decibel loss) over sets of frequencies. As a consequence, our analyses inevitably start from the assumption that for an individual patient percentile values at various frequencies correlate perfectly, i.e. the same patient will be found at the same percentile for measurements across all frequencies. However, we validated this assumption by cross-referencing data from prospective surveys14. A final limitation in the Norwegian data is the absence of information on asymmetric hearing loss, which may lead our analyses to overestimate the number of patients eligible for bilaterally fitted devices.
- It has to be emphasized that estimates of populations qualifying for reimbursement are maximum estimates as confirmed by empirical prevalence studies,[18] given that with regard to the reimbursement of unilateral and bilateral fittings additional criteria beyond registered audiometric criteria are taken into account (see also chapter 6) possibly restricting the population qualifying for reimbursed hearing aids based solely on audiometric values. Nevertheless this methodological drawback does not invalidate our analyses as our main focus lies on the assessment of relative budgetary changes over time dependent on demographic factors rather than in a precise computation of true population sizes at a given moment.
- The analysis of demographic budget drivers inevitably assumes 2006 consumption patterns for age and gender groups can be extrapolated – ceteris paribus- to future years. In doing so, no allowance is made in our baseline simulation for dynamic (e.g. "generational") effects that will most likely occur.

7.4.2 Discussion

Our analyses raised various points meriting further thought and research. First, there appears to be a tendency toward a (proportionally) higher use of bilateral hearing aid fittings compared to unilateral hearing aid fittings. Moreover, the use of bilateral hearing aid fittings seems to be more distinct in the eastern part of Belgium. Second, the stake held by female patients in the RIZIV/INAMI budget diverges considerably from their proportional presence among (modelled numbers of) patients eligible for hearing aid reimbursement. Third, going by current consumption patterns, projected demographic trends alone are estimated to cause a annual real growth rate of 1,6% over the next decades, resulting in a 46% increase in the budget for patients aged 20-89 by 2030. Fourth, a comparison between Germany and Belgium based on audiometric coverage criteria showed Belgian reimbursement criteria to be rather restrictive. Finally, it was shown that altering current Belgian reimbursement criteria with regard to minimal hearing threshold levels and tested frequency sets has a substantial impact on the size of the eligible patient population as well as its age and sex composition, which may raise questions of equity (access to labour market, etc.).

Given the above elements, we conclude research on the relative benefits of unilateral versus bilateral hearing aid fittings and the benefits of a hearing aid at different degrees of hearing impairment would be of particular interest to policy makers given current reimbursement practices.

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14 Taking prevalence data from 6 national surveys for average hearing loss equal or higher than 25 decibel in the best ear over the 0,5, 1, 2 and 4 KHz frequencies as reported in a review by Shield 2006[18] we find our corresponding simulation (17,8% of adults aged 20-89) to be rather on the mark as published prevalence rates range from 14,3% of adults aged 30-50 (Denmark, 2000) to 17,1% of people aged 18 and more (Italy, 1996). Given the different age categories at stake and the fact our data do not allow distinguishing best ear measurements our estimates seem reliably close to empirically observed prevalences.

Key points

- **The overall RIZIV/INAMI budget for non-implanted hearing aids amounts to €20 million.**
- **The annual number of reimbursed bilateral hearing aid fittings has increased with 25% between 1995 and 2005 to around 15 000 (=30 000 devices), while the yearly number of unilateral fittings slightly diminished to around 10 000 devices. In 2006, 61% of hearing aids were bilateral fittings.**
- **In 2006, bilateral hearing aid fittings account for three quarters of all devices in adults.**
- **We observe a Belgian east-west divide with more frequent use of bilaterally fitted hearing aids in the eastern part.**
- **Due to demographic changes alone, the population of patients aged 20 to 89 and potentially eligible for a hearing aid will increase from 700 000 in 2006 to 1 000 000 in 2030, with approximately half of these patients also meeting criteria for a bilaterally fitted hearing aid. As a consequence, the current RIZIV/INAMI budget for hearing aids is projected to increase by 46% in 2030**
- **Women represent 53% of hearing aid expenses partly due to their longevity. However, this proportion is still higher than would be expected from the epidemiology of hearing loss and demography.**
- **Compared to the German insurance scheme, the Belgian reimbursement criteria seem more restrictive. Altering the minimal Hearing Thresholds Levels from the current 40, to eiter 30 or 50 dBHTL produces a wide variation in eligible patient population sizes: a 69% increase and 93% decrease respectively.**
- **The size of the eligible patient population and the stake held by younger patients (below 60 years) are remarkably sensitive to alterations in the tested frequency sets.**

8 GENERAL DISCUSSION

8.1 THE ISSUE

Hearing loss is one of the most common chronic illnesses and is strongly associated with aging. In international studies it was estimated that some degree of hearing loss affects more than half of all persons between the ages of 61 and 70 and up to 84% of people after the age of 70. But, this prevalence obviously depends upon the precise criteria and definitions used. Taking the criteria based on measured hearing loss levels applied by the Belgian public health care payer RIZIV/INAMI as a guide, the population affected in Belgium would be well over 700 000 people. This underlines the considerable societal impact of hearing impairment.

Data from several countries show that only a small proportion of the population qualifying for hearing aids (HA) reimbursement actually opts to buy them. Data gathered in this report show that the number of persons per annually reimbursed hearing aids in Belgium is low, compared to some other countries: 131 residents per reimbursed HA in Switzerland (2005) as compared to 161 in Luxemburg (2006) and 224 in Belgium (2006). An international comparison of the number of hearing aids delivered per head of the population puts Belgium 10th among 12 compared OECD countries providing public coverage for hearing aids in adults. Our simulation based on audiometric reimbursement criteria indicates that the population eligible for hearing aid reimbursement in Belgium would grow with 36% were German criteria to apply. Our simulation also predicts that, only due to demographic changes, the budget for hearing aids will increase with a real growth rate of 1.6% per year during the next decades, assuming no other changes occur.

8.2 RESULTS

Assessing the performance of the current Belgian policy on providing and reimbursing hearing aids requires a comprehensive assessment of the scientific literature for evidence on efficacy and cost-effectiveness. It also needs an in-depth analysis of the Belgian and international market for hearing aids, a discussion of policy choices in other countries, price comparisons, and a review of possible consequences for current and future health care budgets.

8.2.1 Scientific literature

The available literature on the clinical effectiveness of hearing aids does not allow establishing evidence-based recommendations. Only few papers provide high level evidence, and even those present major methodological flaws. Moreover, those studies present a great heterogeneity both in terms of methods and technical parameters tested, precluding meaningful meta-analyses. The analysed studies often compared one specific hearing aid aspect: compression circuit types, digital versus analogue hearing aids, programmable versus non programmable analogue hearing aids, effect of changes in time compression and/or in high frequencies emphasis, directional versus omnidirectional microphones.

The results of our review are consistent with previous reviews. The discrepancy of results between tests done in the audiological laboratory and questionnaires on hearing-related or on health-related quality of life was often reported. In general, non-linear HA were preferred to linear ones and digital HA are preferred to analogue HA although the evidence of benefit is weak. Directional HA produce improved hearing performances over omnidirectional HA, although the listening environment influences greatly such performance. All articles tried to study one specific parameter and showed that the more complex characteristic (non-linear v.s. linear amplification, digital v.s. analogue sound processing or digitally programmed v.s. not digitally programmed hearing aids) is frequently better scored by patients than the less complex one. In the studies there was also great variation in the efficacy/effectiveness assessment in relation to specific patient characteristics not only hearing related (age, severity or duration of the hearing loss), but also lifestyle and living environment.

The most important improvements in hearing aid technology have been described and assessed in this report. It is interesting to note that most of these features are already present in so-called 'middle technology' hearing aids, available from around €1400.

Cost-effectiveness of hearing aids could not be demonstrated in the few studies that have been performed. The main raison is that the QoL questionnaires that were used in those studies did not show an impact on the generic quality of life, which might be due to the choice for the EQ-5D instrument in which audition as a dimension is not measured, as opposed to, for example, the HUI3 instrument. Given the limitations of the available studies in terms of quality and relevance to our research question, no evidenced-based conclusion can be made for the cost-effectiveness of hearing aids.

8.2.2 Market analysis

Key information was often confidential making any analysis of the market for hearing aids a challenge. The few data at hand show that the global market for hearing aid manufacturers could be seen as moderately concentrated in the early nineties and has undergone even further concentration through mergers and acquisitions ever since. At present, six manufacturers account for 90% of all hearing aid devices on the Belgian market.

Moreover, almost no price competition can be observed on the Belgian retail market. Suggested retail prices of HA are published by importers but dispensers are, in theory, free to sell HA at other prices. However, prices do not vary among dispensers and the most frequently sold HA are not the cheapest but are priced above €1000, over two times the established public lump sum reimbursement.

This situation is due to several factors. On the supply side the market is an oligopoly, obstructing normal free market mechanisms to a considerable extent. Moreover, audioprothesists directly receive a proportion of the HA prices; the exact magnitude of this proportion is kept confidential. On the demand side it is important to understand that demand is relatively inelastic to price because hearing aids are seen as necessity goods and patients find themselves ill-placed to assess price differences.

Therefore, the market for hearing aid devices warrants close scrutiny by public authorities in order to guarantee its proper functioning.

8.2.3 International comparisons

8.2.3.1 Reimbursement policy

Reimbursement conditions for hearing aids vary strongly between the eight European countries compared in this report. In countries like Denmark, Luxemburg and the UK, hearing aids are fully reimbursed, while in countries like Spain, no public reimbursement is available. It should be emphasized that the former countries all limit the choice of publicly reimbursed hearing aids on offer, through listing hearing aids eligible for reimbursement, either by product recognition (Luxemburg) or through public tendering schemes (UK and Denmark).

Among countries with lump sum reimbursement schemes (meant to reimburse both the device and the delivery services), Belgium reimburses a lump sum which is similar to that of neighbouring countries Germany and the Netherlands and substantially higher than the current reimbursement in France. The overall Swiss reimbursement levels seem more generous than the Belgian ones but are less favourable for retired persons than for people at younger ages.

Some of the specific regulations applying in other countries might be a source of inspiration for Belgian policy makers. For example, testing of several devices, including cheaper devices that would eventually not require any patient co-payment is mandatory in Germany and Switzerland. Other countries, such as the UK and Denmark have public tendering procedures, or make to some extend a preliminary choice and have testing procedures performed by a public body (SAP, Luxembourg). Switzerland has a split lump sum system, separating reimbursement for the HA device from the reimbursement of the actual HA fitting and testing procedures.

Another interesting feature is the direct mail order system with manufacturers/assemblers supplying directly at the ENT's practice, available in Germany.

As a final point of interest we might learn from the Swiss experience with a hearing aid reimbursement scheme based on a three-level patient severity scale, which takes psycho-social factors into account for determining the most suited patient treatment. A 2007 report by EFK, a Swiss public body responsible for monitoring public finances, advocates the abolition of this patient three-level reimbursement scheme, which came into practice on April 1st 1999, as this scheme seems to be "expensive and not well founded". The scheme seems to cause an upward shift in the reported severity of patient cases, causing an increase of the budgetary stake of hearing aid expenses for the highest patient case category from 36% in 2001 to 50% in 2005. The report argues further that no straightforward relation between patient case severity and the necessary treatment costs can be determined. Therefore, EFK suggests replacing the current Swiss scheme by a uniform lump sum scheme, allowing for exceptions based on individual patient files.

8.2.3.2 Observed price levels

Prices were compared between Belgium and seven other countries for devices identified as representative of the Belgian market by industry contacts. These international price comparisons must be interpreted with extreme caution as prices sometimes include different warranty periods, accessories, services etc.

In spite of these methodological reservations, the comparison shows a strong variation of prices across countries. The average coefficient of variation for compared products across the country sample is 21% and the average factor separating lowest from highest prices is around 1.8.

Out of 46 product comparisons, Belgian prices were found to be higher for 37 products. When comparing with specific countries, this observation is even more striking; for Denmark (for 9 out of 10 comparisons Belgian prices were higher), the Netherlands (7/8), Switzerland (6/7), the UK (5/5) and France (5/6). For the comparison with Switzerland, however, it should be stressed that the overall lump sum reimbursement is split into a part meant to reimburse delivery services and another part meant for the device itself. The part of the reimbursement for the devices has been shown to be lower for most Swiss patients when compared to the Belgian lump sum, but we'd like to stress that this Belgian price includes services by the audioprothesist.

8.2.3.3 Interaction between price levels and public policy

Possible comparisons for low cost devices were too scarce to either validate or invalidate the hypothesis that lump sum fees would lead to price alignment in this product segment.

However, HA prices are remarkably variable for such a standardized product coming from one producer, raising the suspicion that the observed price levels are more influenced by policy-related factors than by normal free market mechanisms. This would explain the finding that retail prices in countries also purchasing hearing aids through public tendering schemes are often lower than those applying in Belgium.

8.2.4 Budgetary explorations

The overall RIZIV/INAMI budget for non-implanted hearing aid care amounts to €20 million or 0.1% of the Belgian public healthcare reimbursement budget in 2006. Hearing aids in adults make up over 95% of this budget. Women represent 53% of hearing aid users, more than would be expected based on combining hearing impairment prevalence and demography.

The annual number of reimbursed bilateral hearing aid fittings has risen with 25% between 1995 and 2005 to around 15 000 (corresponding to 30 000 devices), while the yearly number of reimbursed unilateral hearing aid fittings slightly diminished to around 10 000 devices. In all, bilateral hearing aid fittings account for three quarters of devices in adults. A Belgian east-west divide can be observed in utilisation patterns whereby the eastern part of Belgium displays a markedly higher use of bilaterally fitted hearing aids.

Based on a simulation model fed with data from a large-scale epidemiologic survey in the Norwegian general population comprising over 50 000 individuals, our report finds that the Belgian population aged 20 to 89 year and eligible for a hearing aid, is expected to increase from around 700 000 in 2006 to over 1 000 000 in 2030. Approximately 50% of these patients also meet the additional criteria for bilaterally fitted hearing aids. After correction for empirically observed relative consumption rate differences between age and gender patient groups, the current RIZIV/INAMI budget is projected to increase by 46% in the year 2030, corresponding to a long term real growth rate of 1.6%. It should be stressed that these are static budgetary extrapolations based on 2006 observations and that they capture only the most probable evolution of the budget depending on demographic changes only.

Further simulations indicate that altering the current minimal hearing thresholds produces an important change in eligible patient population sizes. Moreover, the size of the eligible patient population and the stake held by younger patients (below age 60) are remarkably sensitive to alterations in the tested frequency sets, which raises questions with regard to overall equity, such as equal access to the labour market, etc.

8.3 CONCLUSION

Findings from the currently available scientific literature add little to the policy debate on the reimbursement of hearing aids. At present, there is still uncertainty about evidence-based effective and cost-effective best practice. This seems to be confirmed by the Swiss policy maker's experience, as a very elaborate policy framework linking patient severity to tailored hearing aid reimbursement was found to fail its initial purpose.

Therefore, raising current overall reimbursement levels will not necessarily generate genuine additional benefits for patients. Current Belgian reimbursement levels are similar to the Dutch fees, slightly lower than the German ones and higher than the applying French fees. As a result, it cannot be concluded that Belgian fees are substantially lower when compared to neighbouring countries with lump sum reimbursements.

There are indications that price levels of HA devices are partly influenced by reimbursement-policy related factors and not only by normal free market mechanisms. This might leave room for improvement, and some of the reimbursement regulations in other countries might inspire our policy makers and help create a more transparent hearing aid market.

Current Belgian reimbursement criteria are relatively strict compared to other countries and a possible policy could be to change current reimbursement criteria. This could for instance allow more people of working age the access to hearing aids.

These kinds of policy measures should be publicly debated. Ideally, this debate should be enriched by further research on the real benefits of a hearing aids at different degrees of hearing impairment and the relative benefits of bilateral versus unilateral hearing aid fittings where remarkable variations of use are observed both nationally in the different regions of this country, and internationally.

9 APPENDIX

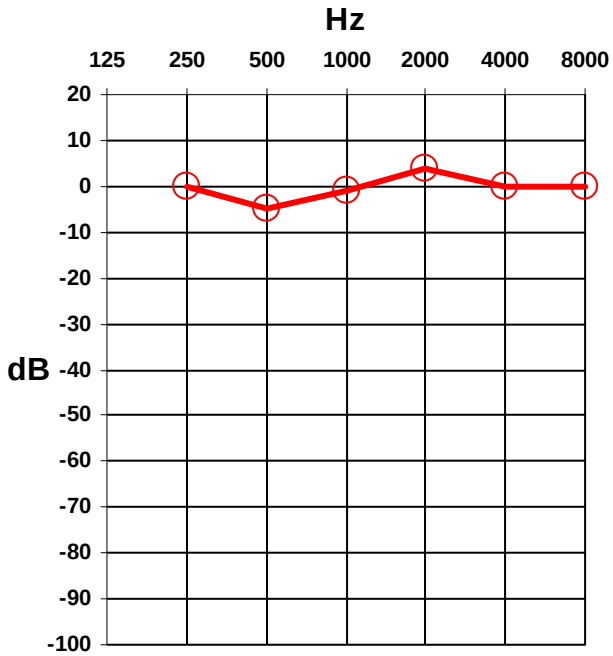
APPENDIX TO CHAPTER I (INTRODUCTION)

RAPPEL DE PHYSIOLOGIE DE L'AUDITION

Chez le sujet normo-entendant (Figure 32), les vibrations sonores sont transmises à la cochlée par le complexe tympan-osselets. Suivant la fréquence du son, la mise en vibration du labyrinthe sera maximale à la base, si la fréquence est aiguë ou plus près de l'apex, si la fréquence est grave. A cet endroit de vibration maximale, les cellules ciliées activées analysent la fréquence, l'intensité et la durée du son. Elles génèrent des potentiels d'action, remontant les fibres auditives, de relais en relais, jusqu'au cortex.

Au niveau cochléaire n'a lieu que l'analyse et le transcodage du son. Sa reconnaissance est un phénomène central : c'est le cerveau qui donne un sens à l'information auditive, en fonction de ce qu'il a mis en mémoire ou des apprentissages.

Figure 32: Normal hearing.



Les tests auditifs étudient l'audition en stimulant la cochlée soit par voie aérienne, soit par voie osseuse.

Par voie aérienne, la vibration sonore est envoyée à l'oreille externe, qui va la transmettre à la cochlée par le complexe tympano-ossiculaire. Il s'agit de l'audition « naturelle ». La transmission sonore sera entravée par tout obstacle complet dans l'oreille externe (bouchon complet de cérumen, aplasie majeure des oreilles), ou obstacle partiel au niveau du tympan (perforation) ou des osselets (lyse, ankylose, malformation). On parlera de surdité de transmission (Figure 33). Une atteinte de l'oreille interne (ou plus rarement rétrocochléaire) ne permettra pas une transformation des informations sonores en potentiels d'action (transduction cochléaire). Il s'agit de surdité de perception ou neuro-sensorielle (Figure 34).

Figure 33: Conductive or transmission hearing loss.

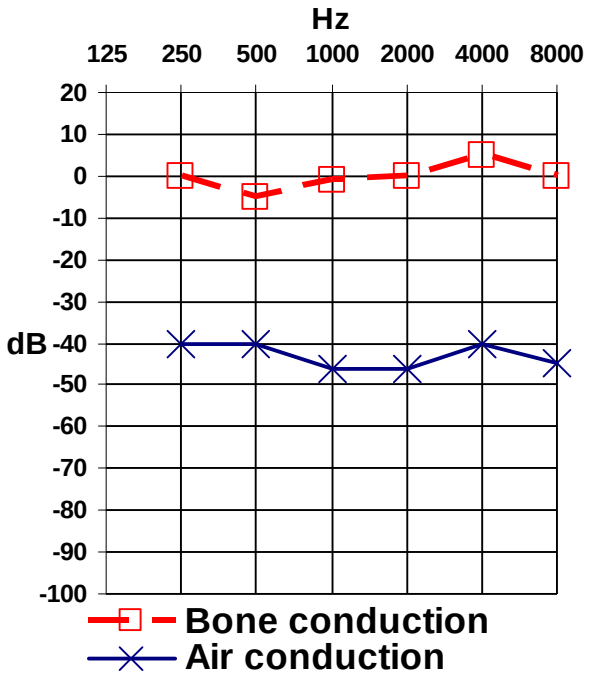
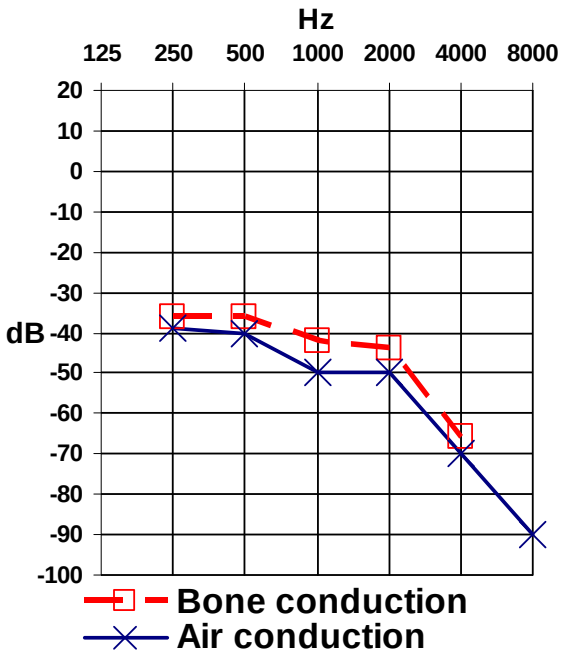


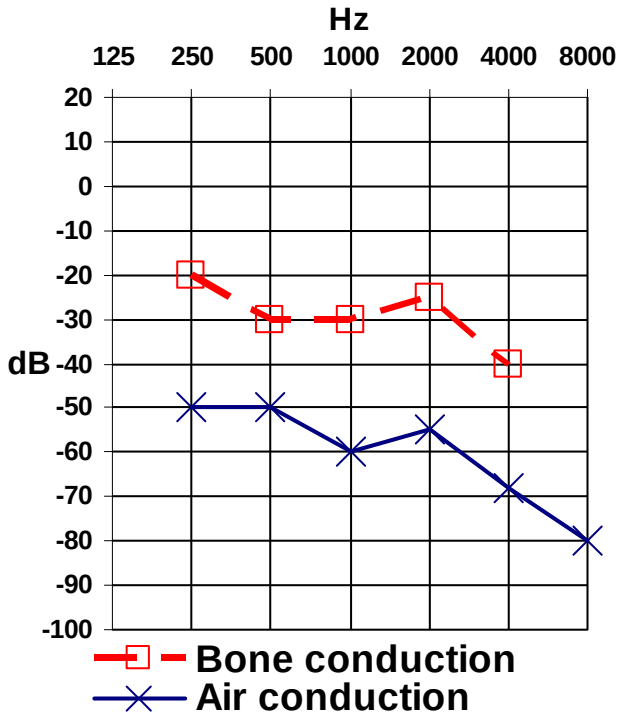
Figure 34: Neurosensorial hearing loss.



Par voie osseuse la vibration sonore est transmise directement à la cochlée, grâce à un vibrateur, qui fait vibrer le crâne. Le son peut par cette voie atteindre directement l'oreille interne, même en présence d'une entrave dans les oreilles externes ou moyennes : surdité de transmission (Figure 33). Dans ce cas, le sujet sera sourd en voie aérienne mais normo-entendant en voie osseuse. L'audition en conduction osseuse est anormale en cas de problèmes d'oreille interne le plus souvent), ou sur le nerf auditif (neuropathie auditive, neurinome), ou sur les voies auditives plus centrales (plus rares) : surdité neurosensorielle ou de perception (Figure 34).

Les surdités mixtes associent atteinte de transmission et de perception (Figure 35).

Figure 35: Mixed hearing loss.



La surdité de transmission est une perte d'audition quantitative: les seuils auditifs augmentent, il faut que la parole soit présentée à une intensité plus foret ou porter un appareil auditif pour que la parole soit correctement comprise.

La surdité de perception est une perte d'audition non seulement quantitative mais également qualitative: la perte des cellules ciliées ne permet plus une analyse correcte des sons. Des distorsions auditives sont associées à l'augmentation des seuils, distorsions qui ne disparaissent pas avec l'amplification des sons présentés à l'oreille. La parole, même amplifiée, reste imparfaitement discriminée. La perte de qualité est corrélée à l'importance de la perte d'audition.

En résumé: à niveau de seuils auditifs identique, le handicap auditif du sujet sera plus important en cas de surdité de perception que de transmission.

TESTS SUBJECTIFS

Ces tests demandent la participation active du sujet.

Acoumétrie

Ces tests sont réalisés en utilisant un diapason : si on le frappe, il émet une vibration à une fréquence caractéristique, qui peut être présentée par voie aérienne (en plaçant les bras du diapason devant le méat auditif externe), ou par voie osseuse (en plaçant le pied du diapason sur un os du crâne).

Ces tests servent à confirmer le caractère perceptionnel ou transmissionnel d'une surdité (Rinne, Weber). Ils permettent également de confirmer une ankylose stapédo-vestibulaire, comme dans l'otospongiose (Lewis, Bonnier).

Audiométrie tonale conventionnelle

Ce test recherche chez un sujet le seuil de perception, exprimé en dBHL ou dBHTL, de sons purs de fréquence variant de 125 à 8000 Hz (Figure 36).

Il peut être réalisé en voie aérienne ou en voie osseuse. En voie aérienne, le son peut être présenté soit par un écouteur placé dans le conduit ou dans la coquille d'un casque auditif, soit par un haut parleur placé à distance du sujet (test en champ libre). Dans ce dernier cas, l'audition est testée dans des conditions plus « naturelles ».

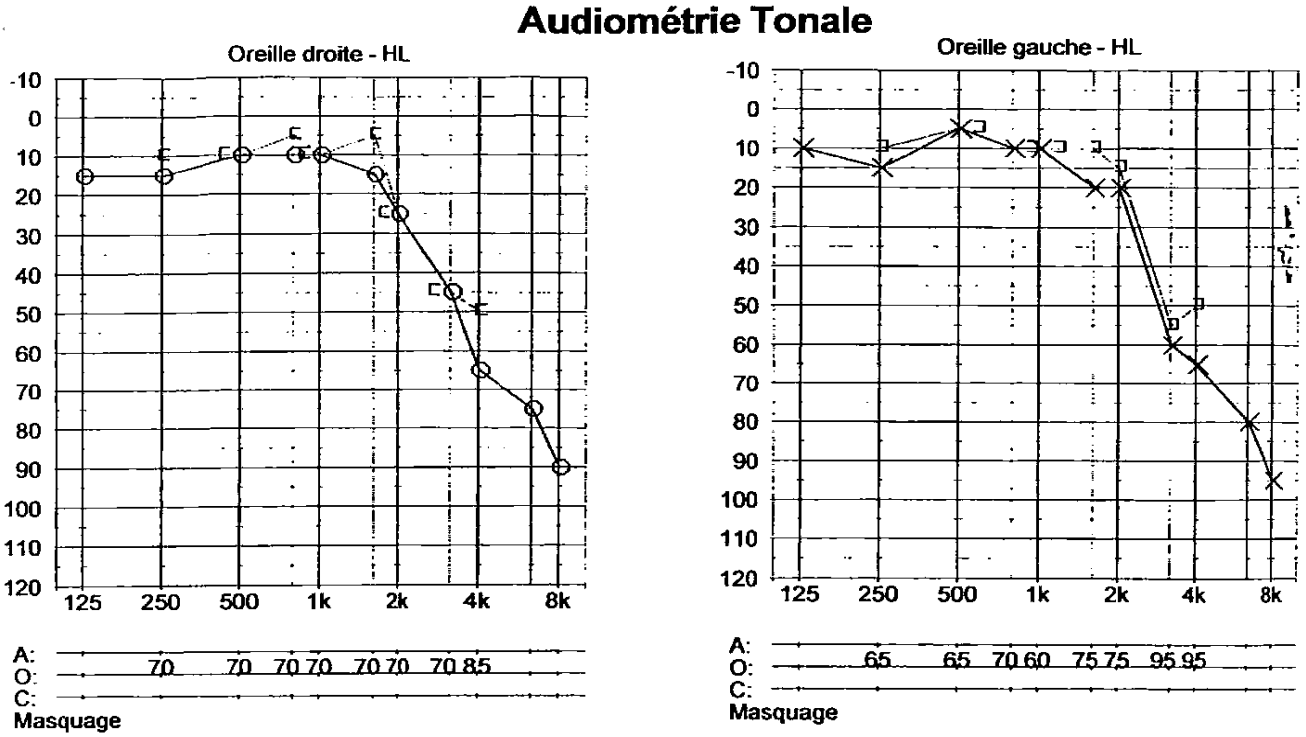
Le test au casque masque les difficultés que peuvent rencontrer certains sujets ne supportant pas les réverbérations des sons. Le champ libre permet également une stimulation des deux oreilles (stimulation stéréophonique).

Il devrait être réalisé idéalement en cabine insonorisée pour que les conditions de test soient contrôlables et reproductibles.

Ce test permet de diagnostiquer le niveau et le type de surdité.

La précision et la fiabilité des seuils demandent le respect des procédures de test, et en particulier des règles de masking ou masquage ou assourdissement : il faut être certain que les seuils mesurés sont ceux de l'oreille testée et non de l'autre. Le non respect de ces procédures conduit à l'enregistrement de courbes fantômes.

Figure 36: Sloping hearing loss.



La classification de la surdité se fait selon les normes du BIAP, en utilisant la moyenne des seuils sur 500, 1000, 2000 et 4000 Hz, sur la meilleure oreille (avec une pondération en cas d'asymétrie importante). La surdité est dite légère si les seuils sont compris entre 20 et 40 dB, moyenne entre 40 et 70 dB, sévère entre 70 et 90 dB, et profonde, si ils sont supérieurs ou égaux à 90 dB.

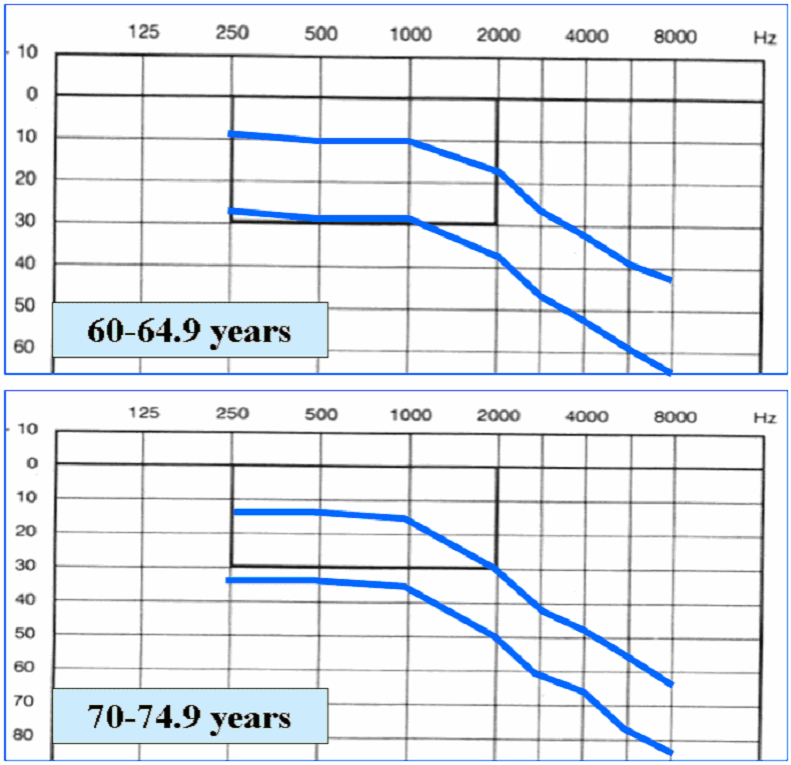
Les conséquences des surdités congénitales ou d'installation précoce sont très dépendantes de leur profondeur. Une surdité légère donnera un retard de développement du langage qui peut passer inaperçu et des confusions auditives. Une surdité moyenne donnera les mêmes problèmes mais de façon plus prononcés. En cas de surdité sévère, le langage oral ne s'installera pas sans prise en charge. La surdité profonde non prise en charge précocement donne une surdi-mutité.

La prise en charge doit être très précoce pour limiter au maximum la durée de privation auditive et le manque de communication fonctionnelle. Un dépistage néonatal de la surdité est une nécessité et un droit car le retard de diagnostic a des conséquences irréversibles sur l'avenir scolaire, professionnel et social de l'enfant. Les surdités acquises à l'âge adulte « n' »ont des conséquences « que » sur la communication auditivo-orale avec les conséquences sociales connues.

Les surdités de transmission pure peuvent toucher toutes les fréquences mais plus souvent les graves. Elles atteignent au maximum 60 dB (surdité moyenne).

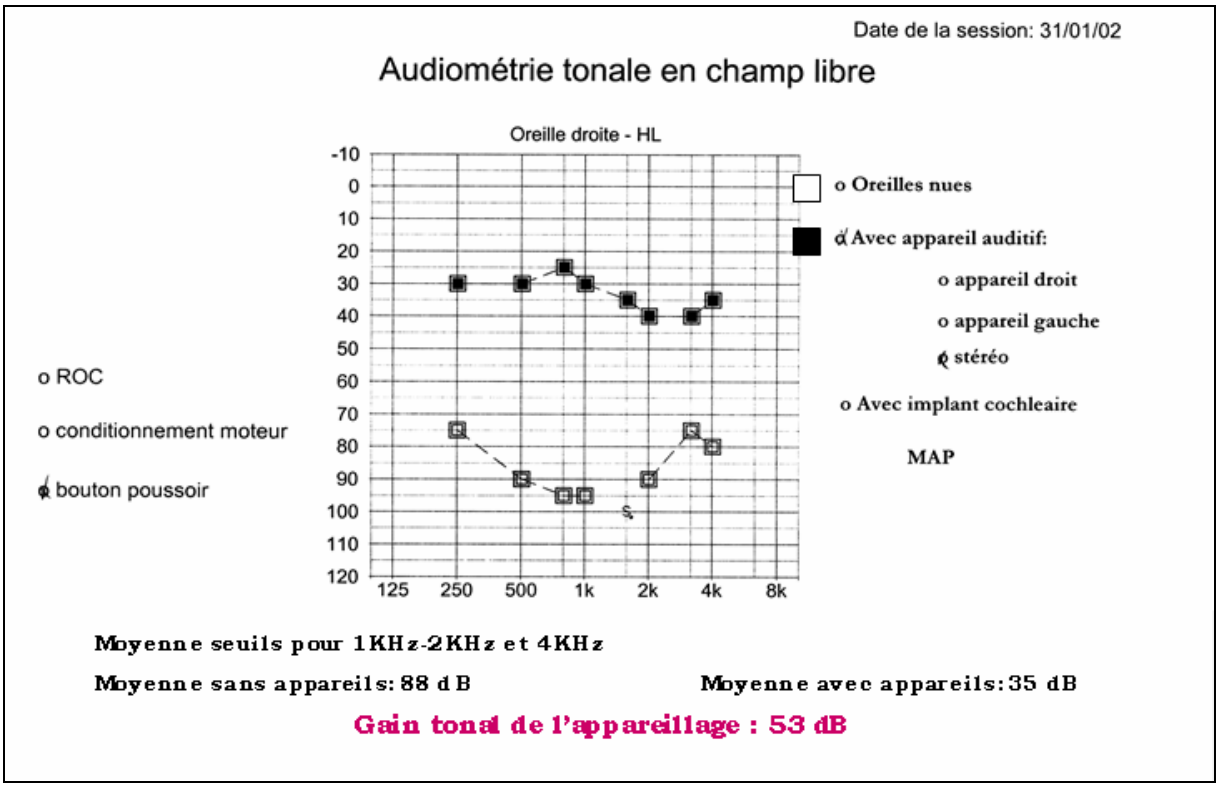
Les surdités de perception peuvent également toucher toutes les fréquences mais plus souvent les aigues, par exemple en cas de presbyacousie ou de surdité professionnelle sur exposition aux bruits. Elles peuvent aller de légère à profonde (Figure 37).

Figure 37: Presbycusis.



En cas d'appareillage auditif (graphique « audiométrie tonale »), le gain prothétique est calculé en faisant la soustraction entre les seuils moyens calculés avec (carrés foncés) et sans appareil (carrés clairs), sur les fréquences 1000, 2000 et 4000 Hz.

Figure 38: Mesure du gain en tonale.



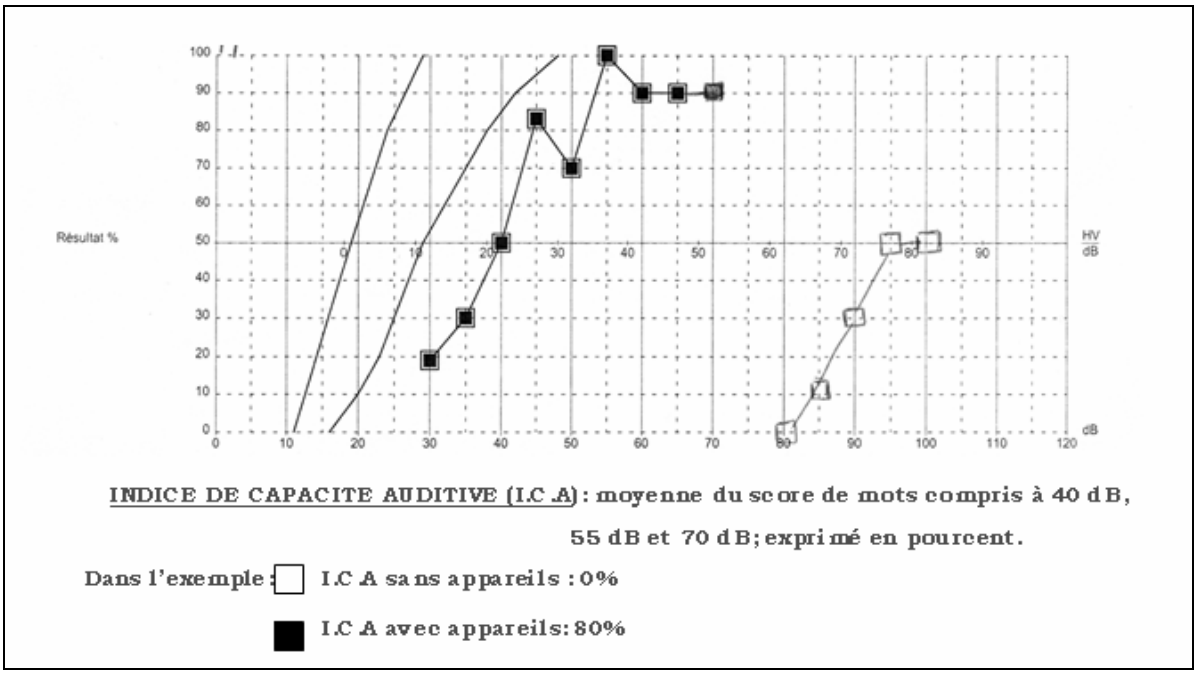
AUDIOMÉTRIE VOCALE

Le matériel de test est composé de mots, phonèmes ou phrases. Il s'agit d'une étude de la perception complète des composants de la parole. Elle est complémentaire de l'audiométrie tonale qui présente des sons purs, peu rencontrés en tant que tel dans la vie de tous les jours.

Habituellement, il existe une concordance entre les seuils en audiométrie tonale et vocale. Une discordance est un signe de distorsions auditives handicapantes dans le vie quotidienne.

La comparaison de l'intelligibilité de mots mesurée avec et sans aide auditive permet de calculer le gain prothétique en audiométrie vocale.

Figure 39: Mesure du gain en vocale.



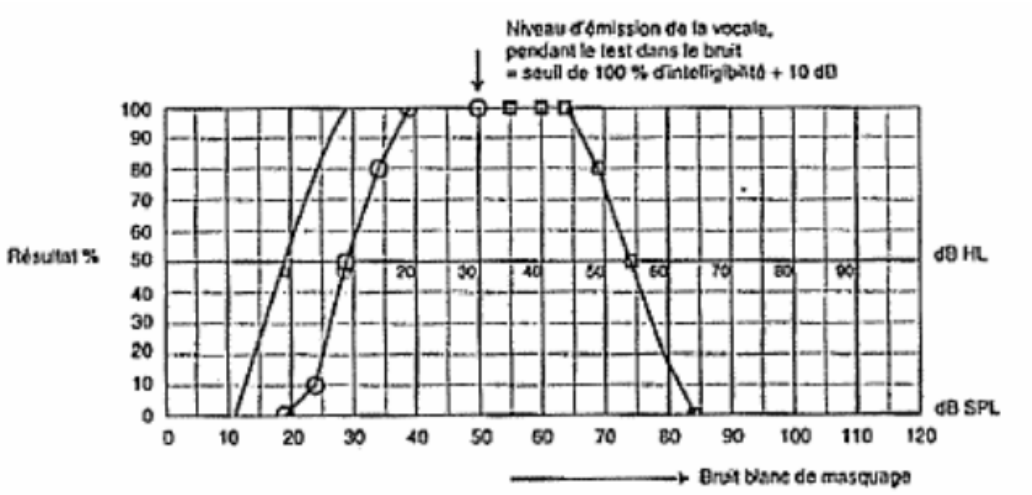
TESTS SPÉCIAUX

Audiométries dans le bruit

Différents tests audiométriques ont été développés pour étudier la résistance de l'intelligibilité de la parole dans le bruit. S'il va de soi que les sourds de perception ont souvent une intelligibilité qui s'effondre dans le bruit, il est moins connu que la même chose peut s'observer chez des sujets « non sourds », présentant par ailleurs une audiométrie dans le calme normale. Ces sujets ont de troubles de compréhension s'ils se trouvent confrontés à des réunions avec plusieurs interlocuteurs, à des discussions dans des endroits bruyants, voire à une scolarisation dans une classe bruyante.

Habituellement, nous pouvons résister à un bruit dépassant la parole de maximum 15 dB. Au-delà notre intelligibilité chute de façon drastique. Chez les sujets intolérants au bruit, l'intelligibilité peut s'effondre même si le bruit est présenté à l'intensité ou en dessous de l'intensité de la parole.

Figure 40: Audiométrie vocale dans le bruit.



% de mots compris, présentés à 50 dB avec du bruit dont l'intensité augmente de 55 à 85 dB: l'intelligibilité des mots diminue progressivement avec l'augmentation du bruit.

L'audition dans le bruit dépend fortement des capacités d'audition stéréophonique. En cas de cophose unilatérale, l'intelligibilité dans le bruit est très perturbée. L'adaptation d'un appareil auditif cross en voie osseuse de type BAHA permet d'améliorer de façon très significative cette capacité d'audition dans le bruit : l'appareil est implanté, de façon transcutanée, dans le rocher du côté sourd, le microphone permet de capter les sons se présentant du côté cophotique, l'implant fait vibrer le crâne, et dès lors la cochlée controlatérale saine. Le sujet entend par sa seule oreille fonctionnelle les sons arrivants de tout l'espace auditif.

Test de localisation

Ce test permet d'étudier les capacités de localisation de la source sonore, ce qui nécessite une audition binaurale. Il est utilisé pour démontrer l'apport d'une adaptation auditive bilatérale.

Tests auditifs centraux.

Les tests les plus utilisés sont repris de la batterie auditive centrale développée par JP Demanez de Liège. Elle étudie la discrimination phonémique dans le calme et dans le bruit, l'aptitude à traiter des informations différentes arrivant en même temps dans les deux oreilles (aptitudes dichotiques), la capacités de détecter des variations de fréquences et durées, et les capacités de démasquage apportées par l'audition binaurale stéréophonique (MLD).

Ces tests peuvent être perturbés avec des audiométries conventionnelles par ailleurs retrouvées normales, en particulier chez les enfants présentant des troubles des acquisitions scolaires.

Quality of life questionnaires

Table 35: Description of hearing-related questionnaires.

	PHAB	APHAB	HHIE	HHIE-S	COSI	SADL	GHABP	AIAD	IOI-HA	EAR scale
Outcome measure	Ease of communication, listening in background noise, listening in reverberant conditions and aversiveness of sounds	Ease of communication, listening in background noise, listening in reverberant conditions and aversiveness of sounds	The emotional and social /situational effects of hearing impairment	The emotional and social /situational effects of hearing impairment	The emotional and social/ situational effects of hearing impairment	Patients satisfaction : Positive effects, service and costs, negative features and personal image	Listening situations	Factors of disability in individual hearing functioning in daily life.	Multiple aspects (social impact, satisfaction degree, …)	Intrinsic hearing issues (hearing in noises,…) and extrinsic issues (comfort, appearance, …)
Type of questions	Pre-determined	Pre-determined	Pre-determined	Pre-determined	Open-response	Pre-determined	Pre-determined + open - response	Pre-determined	Predetermined	Predetermined
Number of items	66	24	25	10	10 (2 questions on 5 open situations)	15	Max 48 + 24	28-30	7	23
Number of levels/item	7	7	3	3	5	7	5	4	5	Rate (0-100)
Administration time	20-30 minutes	10 minutes	10 minutes	< 10 minutes	Little time	/	/	/	/	10 minutes
Pubmed citations	7	43	42	24	4	16	7	6	26	1
Pubmed citations with hearing keywords*	7	43	40	24	3	16	7	6	26	1

* Hearing Aids, Hearing Impaired Persons, Hearing Disorders, Hearing Loss or Rehabilitation of Hearing Impaired

Table 36: Description of general preference-based questionnaires.

	HUI-3	EQ-5D	SF-6D
Outcome measure	Utility score	Utility score	Utility score
Type of items	Pre-determined	Pre-determined	Pre-determined
Number of attributes	8	5	6
Number of levels/attribute	5-6	3	Max 6
Pubmed citations	116	614	61
Pubmed citations and hearing keywords*	5	5	2

* Hearing Aids, Hearing Impaired Persons, Hearing Disorders, Hearing Loss or Rehabilitation of Hearing Impaired

APPENDIX TO CHAPTER 2 (CLINICAL EFFICACY)

SEARCH STRATEGY

Date	06/02/2007
Database (name + access ; eg Medline OVID)	Embase
Date covered (segment)	1995-2007
Search Strategy (attention, for PubMed, check « Details »)	#1. 'hearing aid'/de AND [humans]/lim AND ([adult]/lim OR [aged]/lim) AND [embase]/lim AND [1995-2007]/py (926) #2. effec* (3,851,277) #3. effic* (916,758) #4. #2 OR #3 (4,307,448) #5. #1 AND #4 (332)
Note	

Date	13/02/2007
Database (name + access ; eg Medline OVID)	HTA and NHS-EED (CRD Databases)
Date covered (segment)	1995-2007
Search Strategy (attention, for PubMed, check « Details »)	MeSH Hearing Aids EXPLODE 1 RESTRICT YR 1995 2007 (60)
Note	

Date	13/02/2007
Database (name + access ; eg Medline OVID)	ACP Journal Club (OVID)
Date covered (segment)	1991 to January/February 2007
Search Strategy (attention, for PubMed, check « Details »)	1 hearing aid$.mp. [mp=title, abstract, full text, keywords, caption text] (3) 2 (effic$ or effec$).mp. [mp=title, abstract, full text, keywords, caption text] (2692) 3 1 and 2 (3) 4 limit 3 to yr="1995 - 2007" (1)
Note	

Date	13/02/2007
Database (name + access ; eg Medline OVID)	CINAHL
Date covered (segment)	1982 to February Week 1 2007
Search Strategy (attention, for PubMed, check « Details »)	1 hearing aid$.mp. or Hearing Aids/ (2845) 2 (effic$ or effec$).mp. [mp=title, subject heading word, abstract, instrumentation] (155965) 3 1 and 2 (435) 4 limit 3 to yr="1995 - 2007" (417) 5 limit 4 to (middle age <45 to 64 years> or aged <65 to 79 years> or "aged <80 and over>") (207)
Note	

Date	13/02/2007
Database (name + access ; eg Medline OVID)	Cochrane Database of Systematic Reviews
Date covered (segment)	4th Quarter 2006
Search Strategy (attention, for PubMed, check « Details »)	1 hearing aid$.mp. [mp=title, abstract, full text, keywords, caption text] (22) 2 (effic$ or effec$).mp. [mp=title, abstract, full text, keywords, caption text] (4540) 3 1 and 2 (22) 4 limit 3 to yr="1995 - 2007" (22)
Note	

Date	13/02/2007
Database (name + access ; eg Medline OVID)	Cochrane Central Register of Controlled Trials
Date covered (segment)	1st Quarter 2007
Search Strategy (attention, for PubMed, check « Details »)	1 hearing aid$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] (188) 2 (effic$ or effec$).mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] (269737) 3 1 and 2 (76) 4 limit 3 to yr="1995 - 2007" (52)
Note	

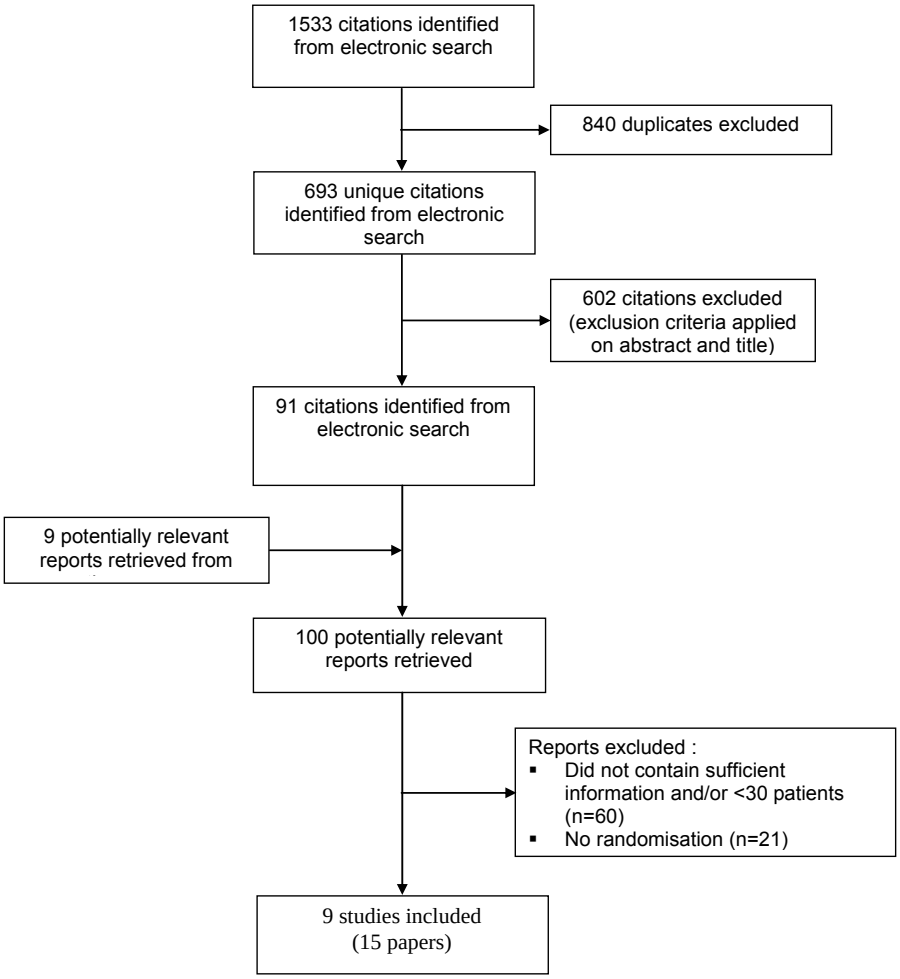
Date	13/02/2007
Database (name + access ; eg Medline OVID)	British Nursing Index
Date covered (segment)	1994 to January 2007
Search Strategy (attention, for PubMed, check « Details »)	1 hearing aid$.mp. [mp=title, abstract, heading words] (26) 2 (effic$ or effec$).mp. [mp=title, abstract, heading words] (9566) 3 1 and 2 (1) 4 limit 3 to yr="1995 - 2006" (1)
Note	

Date	13/02/2007
Database (name + access ; eg Medline OVID)	Database of Abstracts of Reviews of Effects
Date covered (segment)	1st Quarter 2007
Search Strategy (attention, for PubMed, check « Details »)	1 hearing aid$.mp. [mp=title, full text, keywords] (8) 2 (effic$ or effec$).mp. [mp=title, full text, keywords] (4718) 3 1 and 2 (8)
Note	

Date	13/02/2007
Database (name + access ; eg Medline OVID)	MEDLINE(R) In-Process & Other Non-Indexed Citations and MEDLINE(R) (OVID)
Date covered (segment)	1950 to Present
Search Strategy (attention, for PubMed, check « Details »)	1 hearing aid$.mp. [mp=ti, ot, ab, nm, hw] (6150) 2 (effic$ or effec$).mp. [mp=ti, ot, ab, nm, hw] (3273625) 3 1 and 2 (1386) 4 limit 3 to ("all adult (19 plus years)" (748) 5 limit 4 to yr="1995 - 2007" (425)
Note	

FLOW CHART OF LITERATURE RETRIEVAL

Figure 41: Flow chart of literature retrieval clinical efficacy.



QUALITY APPRAISAL OF THE STUDIES

Biering – Sorensen M. et al.[3]

Scand. Audiology 1995; 24: 125-132.

Aim	To compare a non-linear amplifying HA (multifocus) with a traditional linear amplifying (E35F), both of which are targeted towards identical areas of hearing loss and produced by he same manufacturer (Oticon)
Design	Single-blind crossover study with random allocation of the non-linear test HA (T-HA) or linear control HA (C-HA) Interviewers blinded, patients not blinded
Age	Median age 74 years (range 60-80 years)
N	75 patients eligible 52 patients met for information about the study 42 patients decided to participate 32 patients completed the study (3 drop out for health reasons, 1 for travelling distance, 4 for unknown reason, 2 because of monaural fitting)
Method	Experienced users of the linear hearing aid E35F 6 conductive HL and 26 SNHL Monaurally fitted , irrespective of the previous treatment. HA tested during 6-8 weeks Outcome measurements: ▪ Speech recognition score in quiet and in background noise with S/N = 0 dB ▪ Structured interviews by 2 interviewers (1 psychologist and 1 physician) ▪ Follow-up questionnaire one year after to those who preferred the T-A
Results	No significant difference in frequency of HA use in various situations No significant difference in time-related use. Better performance of T-HA on person-to-person conversation in quiet ($p = 0.02$) No significant difference of T-HA on person-to-person conversation in noise T-HA better in terms of brightness of the sound ($p = 0.01$) Loudness in traffic noise lower for T-HA ($p = 0.02$) Amplification obtained with lower acoustic feedback with T-HA ($p = 0.0009$) Internal noise less pronounced with T-HA ($p = 0.03$) No significant difference for the sound quality T-HA easier to manipulate ($p = 0.01$) No significant difference in the speech recognition scores 75% of patients preferred T-HA ($p < 0.05$) The subjects were able to identify the correct HA in 112/192 trials when listening in speech in quiet.

Larson V. et al.[2]

JAMA 2000; 284: 1806-1813.

Aim	'To compare the benefits provided to patients with sensori-neural hearing loss by 3 commonly used hearing aids circuits'.
Design	Double-blind, 3-period, 3-treatment crossover trial conducted from May 1996 to February 1998. Patient blinded, audiologists blinded
Age	Mean age: 67.2 years (range: 29-91)
N	360 patients; 29 dropped out (relocation of residence, withdrawal of patient consent, illness unrelated to hearing, death, sudden change in hearing)
Method	New HA users: half of the patients Binaurally fitted HA: Dyna P2, Phonak, Stafa; with 3 programmable options: linear peak clipper (PC), compression limiter (CL) and wide dynamic range compressor (WDRC) Tested during 3 months for each HA <u>Outcome measurements:</u> ▪ Speech recognition tests: The NU-6, monosyllabic word-recognition test at 62 dB SPL The Connected Speech Test (CST) (48 passages of 8 to 10 sentences) presented in different conditions of intensities and S/N ratios : at 74 dB SPL in quite and in noise(6 talker babble noise), in noise at 52, 62 and 74 dB SPL at S/N -3, 0, +3. The S/N =0 corresponded to the babble level that resulted in 50% performance of CST presented at 62 dB SPL. ▪ Quality rating test: loudness, noise interference, and overall liking of the listening experience using CST sentences presented at 52, 62, 74 dBSPL in quiet and then in noise at S/N + 10 dBSPL. ▪ PHAP/PHAB ▪ Rank-order rating of the 3 HA at the final visit.
Results	▪ Speech recognition tests For Nu-6 : significant improvement of the mean word recognition score by 29% with the 3 HA ($p< 0.001$), WDRC was superior For CST: Significant higher CST scores with the 3 HA ($p<0.001$), WDRC was inferior at 62/0 The mean benefit scores (aided – unaided) showed that the WDRC < CL at 62/0 condition and WDRC > CL for 74/0 condition. When background noise was present, the benefit decreases with the increase of the signal levels, for the 3 circuits. The 3 circuits provide benefice in noisy conditions. ▪ <u>Quality rating test:</u> significant differences in the loudness rating across the 3 HA in quiet and in noise ($p < 0.001$); WDRC more comfortably loud at 52 dB and 74 dB in quiet; no significant differences for noise interference across the 3 HA, except at 62 dB in noise ($p = 0.01$) significant differences for overall liking rating across the 3 HA, at 74 dB in quiet ($p = 0.001$): PC HA less liked

	▪ Subjective assessment: significant difference in PHAP score across the 3 HA ($p < 0.001$) for 2 of the 7 scales: distortion of sounds and aversiveness of environmental sounds (higher frequency of problems with PC) each circuit reduced the frequency of reported problems on 6/7 scales of the PHAB ($p<0.001$) except for aversiveness : for all the circuits, there are more problems in the aided condition. ▪ Ranking of the 3 circuits: first CL (41.6%), second WDRC (29.8% and third PC 28.6%)

Larson V. et al. [31]

Ear and Hearing 2002; 23: 269-276. (cfr Larson 2000)

Aim	'To compare the efficacy of 3 commonly used hearing aids circuits: peak clipping, compression limiting, and wide dynamic range compression'.
Design	Double-blind, 3-period, 3-treatment crossover trial conducted from May 1996 to February 1998. Patient blinded, audiologists blinded
Age	Mean age: 67.2 years (range: 29-91)
N	360 patients; 29 dropped out (relocation of residence, withdrawal of patient consent, illness unrelated to hearing, death, sudden change in hearing)
Method	New HA users : one half of the patients Binaurally fitted HA: Dyna P2, Phonak, Stafa; with 3 programmable options: linear peak clipper (PC), compression limiter (CL) and wide dynamic range compressor (WDRC) Tested during 3 months for each HA Outcome measurements: ▪ Speech recognition tests: The NU-6, monosyllabic word-recognition test at 62 dB SPL The Connected Speech Test (CST) (48 passages of 8 to 10 sentences) presented in different conditions of intensities and S/N ratios : at 74 dB SPL in quite and in noise(6 talker babble noise), in noise at 52, 62 and 74 dB SPL at S/N -3, 0, +3. The S/N =0 corresponded to the babble level that resulted in 50% performance of CST presented at 62 dB SPL. ▪ Quality rating test: loudness, noise interference, and overall liking of the listening experience ▪ PHAP/PHAB ▪ Rank-order rating of the 3 HA at the final visit.
Results	This article presents only a summary of the results

Henderson W., Larson V. et al. [63]

Ear and Hearing 2002; 23: 277-279. (cfr Larson 2000)

Aim	'This article describes the organisation and administration of the NIDCD/VA Hearing Aid Clinical Trial'.
Design	
Age	
N	
Method	
Results	Advantages and disadvantages of a multicenter clinical trial Organisation of the trial History of the NIDCD/VA hearing aid clinical trial Publication process

Shanks J. et al. [65]

Ear and Hearing 2002; 23: 280-289. (cfr Larson 2000)

Aim	'This study compared speech recognition performance on the North western University Auditory Test No 6 (NU-6) and the Connected Speech Test (CST) for 3 hearing aids circuits (peak clipping, compression limiting and wide dynamic range compression) in adults with symmetrical sensorineural hearing loss'.
Design	Double-blind, 3-period, 3-treatment crossover trial conducted from May 1996 to February 1998. Patient blinded, audiologists blinded
Age	Mean age: 67.2 years (range: 29-91)
N	360 patients; 28 dropped out (relocation of residence, withdrawal of patient consent, illness unrelated to hearing, death, sudden change in hearing)
Method	New HA users: half of patients Binaurally fitted HA: Dyna P2, Phonak, Stafa; with 3 programmable options: linear peak clipper (PC), compression limiter (CL) and wide dynamic range compressor (WDRC) Tested during 3 months for each HA Outcome measurements: ▪ Speech recognition tests: The *NU-6*, monosyllabic word-recognition test at 62 dB SPL The *Connected Speech Test (CST)* (48 passages of 8 to 10 sentences) presented in different conditions of intensities and S/N ratios : at 74 dB SPL in quite and in noise(6 talker babble noise), in noise at 52, 62 and 74 dB SPL at S/N -3, 0, +3. The S/N =0 corresponded to the babble level that resulted in 50% performance of CST presented at 62 dB SPL.
Results	▪ NU-6: In unaided conditions, mean performance on NU-6 decreased significantly ($p < 0.008$) across visits. This might be related to increasing reliance on HA use or/and to declining interest in the rather laborious experimental. Mean performance on NU-6 with HA increased to 85 The WRDC resulted in a slight but significant improvement ($p < 0.017$). ▪ CST: Aided performance exceeded unaided performance for all 10 condition

	Aided performance for all speech levels increased as the signal-to-babble ratio improved from –3 dB to 3 dB. Differences in recognition performance on the CST among the 3 HA were small. The CST score obtained with the WDRC in the 62/0 condition was significantly poorer ($p<0.017$). Some interesting interactions between speech level and signal-to-babble ratio for the aided data are apparent. The relationship between speech level and signal-to-babble ratio is complicated further by the degree of hearing loss: <40dB and slope <10dB/octave: PC significantly better at 52/± 3 ($p<0.017$) (n=54) <40dB and slope >10dB/octave: CL significantly better at 62/0($p<0.017$) (n=149) >40dB and slope <10dB/octave: no significant difference (n=91) >40dB and slope >10dB/octave: WDRC significantly better at 52/0 and 52/3 ($p<0.017$) (n=62)

Noffsinger D. et al [64]

Ear and Hearing 2002; 23: 291-300. (cfr Larson 2000)

Aim	'As a part of a large clinical trial that compared three hearing aid circuits using several evaluation methods, judgments about quality of listening experiences were sought from all subjects. Three dimensions were examined: loudness, noise interference and overall liking (quality)'.
Design	Double-blind, 3-period, 3-treatment crossover trial conducted from May 1996 to February 1998. Patient blinded, audiologists blinded
Age	Mean age: 67.2 years (range: 29-91)
N	360 patients; 29 dropped out (relocation of residence, withdrawal of patient consent, illness unrelated to hearing, death, sudden change in hearing)
Method	New HA users: half of patients Binaurally fitted HA: Dyna P2, Phonak, Stafa; with 3 programmable options: linear peak clipper (PC), compression limiter (CL) and wide dynamic range compressor (WDRC) Tested during 3 months for each HA Outcome measurements: *Quality rating test:* loudness, noise interference, and overall liking of the listening experience experience using CST sentences presented at 52, 62, 74 dBSPL in quiet and then in noise at S/N + 10 dBSPL.
Results	*Noise interference*: increases with stimulus levels in all the aided trials and the PC circuit was less noisy for the 62N condition ($p = 0.01$). No other significant difference across circuits. Overall liking: decreases with stimulus levels in all the aided trials and the PC was less liked than either of the other circuits for the 74 dB sentences presented in quiet ($p = 0.001$) *Loudness*: was judged comfortable in all the aided trials only at 62 dB and WDRC more comfortable at both 52 dB and 74 dB ($p=0.001$) (on all patients): In group A: PC less comfortable at 74 dB N ($p = 0.001$) In group B: WDRC more comfortable at 52 dB Q, 74 dB Q and 74 dB N ($p = 0.001$)

	In group C: WDRC more comfortable at 52 dB Q, WDRC and CL more comfortable at 74 dB Q and 74 dB N(p = 0.001) In group D: WDRC more comfortable at 52 dB N (p = 0.001)

Haskell G. et al. [62]

Ear and Hearing 2002; 23: 301-307. (cfr Larson 2000)

Aim	'Subjective measures of performance were assessed on three different hearing aid circuits as a part of a large clinical trial. These measurements included the Profile of Hearing Aid Performance and a subjective ranking of individual preference'.
Design	Double-blind, 3-period, 3-treatment crossover trial conducted from May 1996 to February 1998. Patient blinded, audiologists blinded
Age	Mean age: 67.2 years (range: 29-91)
N	360 patients; 29 dropped out (relocation of residence, withdrawal of patient consent, illness unrelated to hearing, death, sudden change in hearing)
Method	New HA users: half of patients Binaurally fitted HA: Dyna P2, Phonak, Stafa; with 3 programmable options: linear peak clipper (PC), compression limiter (CL) and wide dynamic range compressor (WDRC) Tested during 3 months for each HA <u>Outcome measurements:</u> ▪ PHAP/PHAB ▪ Subjective ranking of individual preference
Results	<u>PHAP</u>: Aversiveness and distortion of sound: significant lower performance of PC In group B: significant lower performance of PC for aversiveness of sound In group C: WDRC significantly worse for familiar talkers <u>Subjective preference</u>: CL preferred by 42% of patients, WDRC by 30% of patients and PC by 29%. The same result is observed in group C, but is not significant in other group.

Bratt G. et al. [61]

Ear and Hearing 2002; 23: 308-315. (cfr Larson 2000)

Aim	'Because of the NIDCD/VA hearing aid clinical trial was conducted across eight clinical sites, rigorous control of the electroacoustic characteristics of the experimental devices was required'.
Design	Double-blind, 3-period, 3-treatment crossover trial conducted from May 1996 to February 1998. Gain and output measures of the 720 hearing aids(HA) , using 2cc coupler and in situ recordings Measures repeated 6 times on each HA across the 9-mo duration of the study to follow the stability and the accuracy of the studied circuits.
Age	Mean age: 67.2 years (range: 29-91)
N	360 patients; 29 dropped out (relocation of residence, withdrawal of patient consent, illness unrelated to hearing, death, sudden change in hearing)
Method	Single channel full concha in-the-ear HA (Phonak Dyna P2), with possible manipulation

	of the volume control by the subject. with 3 programmable options: linear peak clipper (PC), compression limiter (CL) and wide dynamic range compressor (WDRC). Establishment of gain : using the NAL-R formula., in situ recordings of the circuit's frequency response (input signal 65 dB SPL) Real Insertion Gain (RIIG) = real ear aided response (REAR) minus Real Ear Unaided response (REUR) + freedom to adjust the gain in every day life with the volume control. Output establishment: Calculated Real Ear Saturation Response (RESR) target = loudness discomfort levels (LDL in dB HL) to pure tones + the real ear to coupler difference (RECD) . The RECD = real ear aided aided response (REAR) minus 2cc coupler response . RESR verification with an input of 90 dB swept pure tone = RESR curve that is compared to the calculated, allowing adjustments. The HA output is set as high as subjectively tolerated. User comfort controlled at 2 weeks follow up The established RESR is held constant over all subsequent conditions.
Results	2 cc coupler measures: High Frequency Average Output (HFA OSPL-90) and RESR tend to be higher with PC (about 6 dB) and are stable (+/- 4 dB) in 1975 comparisons Gain: HFA full on gain (at 65 dB) are stable (+/- 4 dB) in 1975comparisons Real ear Measures: Gain: no difference of the circuits to achieve NAL-R target and all do well at reaching target through 3 kHz but under-shoot at 4 kHz. Output: RESR of PC higher (about 5 dB), RESR for all the circuits fall below the calculated target in 90% of the cases. Slight upward trend in loudness tolerance over the course of the study. The measures reflect satisfactory stability end accuracy to achieve the intended goals of the study

Nilsson P. et al. [4]

Audiology, 1997; 36: 325-338.

Aim	The aim of our study was to find out whether the non-linear K-amp circuit or the ordinary linear amplification circuit was preferred by the subjects with a double-blind cross-over methods
Design	Double-blind crossover trial Patients blinded, audiologist blinded Random allocation of the HA
Age	Mean years (range: 60-80 years)
N	54 included, 9 drop out for tinnitus, problems handling HA, complicating diseases during the project, uninterested in fulfilling the project, insufficient amplification, inappropriate anatomical conditions.
Method	Experienced HA users

	Monoraurally and binaurally fitted HA: ordinary linear amplification (L-HA), compressive amplification (K-HA) HA tested during 2,5 months Outcome measurements: Insertion gain measurements (not presented in results) Word discrimination test in noise at 75 dBSPL with S/N=0 Structured questionnaire Preference questionnaire
Results	K-HA finally chosen by51% of patients and L-HA by 44% of patients No significant difference for the situation in which the HA are used No significant difference between mono or bilateral fitting No significant difference in the time-use of HA No significant difference in the outcome of speech recognition score in noise Main outcome is the final choice of HA and not the comparison of the 2 HA

Parving A. et al. [66]

Scand Audiol, 1997; 26: 231-239.

Aim	'To compare a current and up-to-date HA with a programmable multi-band full-dynamic range compression behind the ear HA and to compare the subjects' preference for a linear/non-linear amplification mode'
Design	Double blind crossover study for the tested HA: linear versus non-linear amplification mode; patient blinded and interviewer blinded; randomization for amplification mode Patients not blinded for study concerning current HA versus tested HA
Age	Median age: 72 years (range: 22-84)
N	44 patients; 10 dropped out (prefers previous HA, tested HA too weak, outer ear problems, has become seriously ill, has received another HA, unwillingness)
Method	Experienced HA users 8 monaurally fitted, 36 binaurally fitted HA: reference HA, digitally programmable with compression mode amplification, digital with linear mode amplification (ReSound) Tested: 2 months observation period Outcome measurements (to find in Parving 1991) SRS in quiet SRSN with S/N = 10dB, speech signal presented at 55 dB HL Structured questionnaire
Results	No significant difference for situational use of HA No significant difference time-related use of HA Significant preference for the T-HA (32/34 subjects) Significant preference for the non-linear amplification No significant differences for SRSN Time for testing and fitting T-HA = 150 minutes/patients whereas time consumed for R-HA = 90 minutes Added costs of approximately 1800 DKR for T-HA

Wood SA. and Lutman ME. [5]

International Journal of Audiology, 2004; 43: 144-155.

Aim	Comparison of speech recognition performance and self-related benefit from linear analogue and advanced hearing aid users
Design	Single-blind crossover trial stratified by age, sex and degree of hearing loss randomization in 3 groups Patients blinded
Age	Mean 67 years (range: 19-80 years)
N	100 included, 3 drop out for health reasons
Method	New HA users Monaurally fitted 5 HA: 2 single channels linear analogue HA (NHS BE103; NHS BE 38), 3 digital (Danavox Danalogic; Oticon Digifocus; Siemens Prisma) HA tested during 5 weeks Outcome measurements: ▪ Speech testing in noise (FAAF): 2 complete list of 80 items (speech at 65 dBA and SNR + 2 db; speech at 75 db and SNR + 2 db) ▪ APHAB, GHABP ▪ Quality of life: GHSI + visual score ▪ HA diary measures ▪ Preferences
Results	Speech in noise REIG with digital HA is lower at frequencies 0.25 to 2 kHz and higher 3 kHZ ($p<0.001$) Speech recognition is higher with digital HA ($p = 0.001$) (72.0 vs 70.7 at 65 dB; 72.8 vs 69.3 at 75 dB), but there is a difference between the type of digital HA (Siemens prisma > Danavox Danalogic ($p = 0.01$). For NHS HA, speech recognition is better when this HA is tested second ($p = 0.001$). GHABP: higher satisfaction with digital HA ($p> 0.05$): Use (median): 95.8 ana HA vs 100 dig HA Benefit (median): 65.0 ana HA vs 65.6 dig HA Residual disability (median): 21.6 ana HA vs 18.7 dig HA Satisfaction (median): 65.8 ana HA vs 67.8 dig HA APHAB: 36/100 available data, significant differences between unaided and aided conditions on the ease of communication, reverberation, background noise ($p<0.001$) , no difference between the aided conditions for these 3 subscales, the unaided condition gives less aversiveness than aided conditions (digital HA $p<0.01$, NHS HA $p< 0.001$) Quality of life (GHSI): no significant difference between ana HA and dig HA Diary measures: no significant difference between ana HA and dig HA Preferences: dig HA preferred ($p < 0.001$): better sound quality, better performance in noise

Yueh B et al [25]

Arch Otolaryngol Head Neck Surg, 2001; 127: 1197-1204.

Aim	'To compare the relative effectiveness of an ALD, a non programmable HA routinely issued, a programmable aid with a directional microphone against the absence of amplification.'
Design	Randomized controlled trial – 4 arms: No amplification Assistive listening device Standard aid Programmable aid Patients not blinded
Age	Mean age: 68.5 years (range: 50-86)
N	64 patients; 4 dropped out (1 death, 3 unwilling to return for their 3-month follow-up visit)
Method	New HA users Binaurally fitted HA: non programmable non directional HA versus programmable directional HA Follow-up of 3 months Outcome measurements: ▪ Speech recognition score ▪ HHIE ▪ APHAB ▪ Hearing diary ▪ Willingness to pay data
Results	No presentation of results concerning speech recognition scores. Increase of HHIE score: + 17 points for standard HA and + 31 points for program. HA ($p < 0.001$) Increase of APHAB score: +7.7 points for standard HA and + 16.3 points for program HA ($p = 0.01$) Significant difference in use of HA: 8.8h/day for program. HA versus 6.9h:day for standard HA ($p < 0.001$) Substantial differences for willingness to pay: Mean of $40 in case of ALD Mean of $800 in case of standard HA Mean of $2240 in case of programmable HA

van Toor, Verschuure [6]

Int J Audiol 2002 Oct; 41(7): 379-94..

Aim	'To investigate the effects of some pre-programmed settings provided by a manufacturer and to assess them for speech intelligibility in noise and for user satisfaction: effects of different compression time-constants and high frequencies emphasis compression..'
Design	Randomized multicentric cross over study. Comparisons in 3 consecutives experimental periods of 4 weeks: the first 2 were used to assess the compression parameters, the third to assess the effect of tilting of the frequency range.
Age	Mean age: 63 years (range: 34-84)
N	38 patients
Method	Experienced and new HA users Monaurally and binaurally fitted HA: Philipps Spaceline D71-40 BTE Follow-up of 3 months The order of testing of the users was randomized over 2 response characteristics (AUTO and SPIN). The groups were then randomized over the order of comparing the compressions time. First 2 periods were used to compare the 3 compression times randomly assigning listeners to the 2 frequency-shape settings (AVC-NORMAL in the first period, NORMAL-SYLLABIC in the second one or NORMAL-SYLLABIC in the first and AVC-NORMAL in the second one). <u>Outcome measurements:</u> ▪ Measure of Speech-in-noise thresholds of Plomp: SNR at winch 50% of the sentences are correctly repeated in a background masking noises(unmodulated speech noise, modulated speech noise, low frequency car noise) presented at 70 dBA or 20 dB above SPT in quiet. ▪ APHAB
Results	-No overall preference of compression algorithm or tilt was found. -No correlation between best preferred compression algorithm and hearing loss parameters. -A high frequency emphasized frequency response, on average, improves the speech intelligibility in noise more than a flat response. This effect decreases after optimization of the compression times. -Patients using fast compression mode obtained larger improvement in SNR. But they are inter subjects differences and acclimatization effects.

Gatehouse [67]

International Journal of Audiology 2006; 45:130-152

Aim	The aim of this study is to evaluate the benefits of fast-acting WDRC, slow acting AVC and linear fitting.
Design	Double-blind crossover trial with random allocation of the non-linear fitting Subject and experimenter blinded (as far as practicable)
Age	Not mentionned
N	50 included with bilateral symmetric sensorineural HL
Method	• 50 included with bilateral symmetric sensorineural HL • 5 HA fittings: (all five partly linear) - 2 linear reference conditions: One single-channel with volume control (NAL-RP) One two-channel without volume control (LINEAR) - 3 two-channel compression fittings released times in the low-frequency and high frequency channels: SLOW-SLOW FAST-FAST FAST-SLOW • 4 Benefit factors: • Listening comfort (LC), • Satisfaction (S), • Reported intelligibility (RI) • Speech test benefit (STB) These benefit factors are built by factor analysis from: Speech tests: • Using the FAAF (Four alternative Auditory Feature Test) • Speech presentation levels of 55, 65, and 75 dB SPL • Signal to noise ratios of + 5 and +10 dB • Steady-state, ICRA-2 and ICRA-6 noise Self-report measures: • APHAB • SADL • GHABP • HAPQ • Direct visual analogue rating scales
Results	• Listening comfort Superior outcome with each of the non-linear fitting Slow-Slow > Fast-Fast > Fast-Slow

	• Satisfaction Superior outcome with each of the non-linear fitting But no difference amongst the 3 non-linear fittings • Reported Intelligibility Superior outcome with each of the non-linear fitting (Fast-Fast and Fast-Slow) > Slow-Slow • Speech Test Performance Superior outcome with each of the non-linear fitting (Fast-Fast and Fast-Slow) > Slow-Slow • Preference of patients: Listening comfort: 42% preferred Slow-Slow 68% preferred the non-linear fitting Satisfaction: 46% preferred Slow-Slow 82% preferred the non-linear fitting Reported Intelligibility 36% preferred Fast-Slow 74% preferred the non-linear fitting Speech Test Performance 44% preferred Fast-Fast 80% preferred the non-linear fitting

Ricketts T, Lindley G, Henry P [32]

Ear and Hearing 2001;22;348-361

Aim	To evaluate the impact of low-threshold compression and hearing aid style (in-the-ear [ITE] versus behind-the-ear [BTE]) on the directional benefit and performance.
Design	Randomized multicentric cross over study No blinding 5 different models of HA were evaluated: 1 BTE (single-channel, digitally programmable analog instruments) and 4 ITE: a single-channel, digitally programmable analog HA with 2 microphones; a 2-channels, digitally programmable analog HA, with 1 microphone; a 4-channel, digital-signal-processing, with 2 microphones; a 2-channels; a linear with hard peak clipping, analog HA, with 1 microphone Drop-out rate: not reported
Age	Median age: 69.5 years (range: 36-94)
N	47 patients (in 2 centres) with mild-to-moderate sensorineural HI
Method	Experienced and new HA users Binaurally fitted; trademark of HA not reported

	Subjects were fit bilaterally in 18 hearing aid conditions (5 linear and 4 compression prescriptions in both directional and omnidirectional modes). Testing was performed with a single primary sound source and five uncorrelated competing noise sources delivered from a total of 6 speakers. The testing order of the 18 HA conditions was randomized across all subjects. All microphone and fitting conditions were evaluated during sessions separated by at least 1 day. <u>Outcome measurements:</u> ▪ the Connected Speech Test (CST; average speech recognition) and the Hearing in Noise Test (HINT; average sentence reception thresholds in noise) were applied in a moderately room
Results	1. Directional gave better speech recognition than omnidirectional HA in noisy environments ($F=317.1$, $p<0.0001$). The improvement in average speech recognition for subjects fit in directional mode ranged from 13% to 23% over that measured in omnidirectional mode, depending on the particular hearing aid model. The average sentence reception thresholds in noise were between 2.2 and 2.9 dB better for directional than omnidirectional modes. Moreover, the directivity index of each HA was correlated to the relative directional benefit 2. There was no significant interaction between the compression and the microphone type. Compression versus linear processing had no impact on the magnitude of listeners' performance 3.ITE gave better speech recognition than BTE in diffuse noisy environments in both omnidirectional and directional mode.

AUDITORY OUTCOMES MEASUREMENTS

Yueh 2001

- Tonal audiometry
- Speech recognition score: Maryland CNC protocol at 10 dB > HTL 3000 Hz

Larson 2000 (+ Larson 2002, Henderson 2002, Shanks 2002, Noffsinger 2002, Haskell G 2002, Bratt 2002)

2 tests Speech Recognition

- A recorded version of a mono-syllabic word recognition test:
  - NU-6
  - Single loudspreaker face at patient
  - 62 dB SPL
  - NU-6 list contained 50 scoreable items
  - Each item = 2%
- A recorded version of the Connected Speech Test (CST)
  - 48 passages with 8 to 10 sentences that approximate everyday connected discourse.
  - Variety of presentation and background noise levels
  - Loudspeaker at 0° azimuth
  - 74 dB SPL: in quiet and in 3 background noise conditions
  - 52 and 62 dB: in 3 conditions of background noise
  - Noise: multitalker babble (6 subjects)
  - Noise: 45° azimuth left and right
  - Signal/noise: -3, 0, +3 dB
  - S/N = 0: babble level that resuts in 50% performance of CST presented at 62 dB (procedure S/N at 6 dB and decrements of 4 and increments of 2 until correct recognition reaches 50%. At this S/N retest, if score between 34 and 66% = accepted at 0 S/B).

Parving 1997

- Speech recognition threshold monosyllabic word lists
- Maximal Recognition in quite = SRS
- SRS in noise, signal at 55 dB HL and Signal/Noise: +10 dB

Nilsson 1997

- Word discrimination test in noise (Dantale noise), signal/noise = 0, signal = 75 dB
- 50 words for each HA at MCL

Wood 2004

Four Alternative Auditory Feature (FAAF) (Foster and Haggard, 1984):

- Single words from a set of four alternatives composed on the rythme test principe enunciated in a common carrier phrase “Can you hear …… clearly?”.
- 80 items presented in random order.
- Monaural, Non-test ear occluded
- Background noise = stationary Gaussian noise filtered such that its spectrum closely matched the long-term average spectrum of noise
- Speech and noise from the single loudspreaker in front of the test subject at a distance of 1.5 m.

- Noise commence 500 ms before the word and continue 100 ms after the end of each word.
- Steps:
  - 1: familiarization: 12 Words 65 dB (A) in quiet,
  - 2: familiarization: with noise S/N +2 dB (S at 65 (6 items) and 75dBA (6 items)
  - 3: SNR: 80 items, in quiet (Signal=65 dB) and in noise (SNR=+2dB)
    - >50% with SNR+2 dB: this SNR for the remainder of the testing
    - <50% second list with SNR +5dB: SNR +5dB for the remainder of the testing
  - 4: testing:
    - 2 complete lists of 80 item with speech 65 dB and SNR +2dB (or SNR +5 dB)
    - 2 complete lists of 80 items with speech 75 dB and SNR +2 dB (or SNR +5 dB)
- Scores for each speech level = percentage correct/average for each speech level
- NHS: 2 required reduced gain for the higher speech level
- Digital: omnidirectional, noise reduction active

Biering-Sorensen 1995

- Speech recognition score: S?
  - in quiet (SRS)
  - in background noise (SRSN) with a Signal/Noise: 0
- Monosyllabic word list scoring words (DAN-tale)
- Aided SRSN: in a sound field situation
  - Word: 0° azimuth to the subject's right and left ear
  - Noise: through two loudspeaker, 45° azimuth to the subject's right and left ear
  - SRSN measured at the most comfortable loudness level.

Rickets 2001

- Sentence reception thresholds were measured using Hearing in Noise Test (HINT) sentences
- Speech recognition of listerners was evaluated at fixed SNRs using the Connected Speech Test (CST)

PREVIOUS SYSTEMATIC REVIEWS

Main characteristics of systematic reviews

Table 37: Systematic reviews on efficacy/effectiveness of HA.

Author	Main question	n	Inclusion criteria	Main findings	Quality score
Taylor, 2001 [59]	Clinical and cost-effectiveness of digital vs analogue HAs	8 (378 individuals with mild to severe impairment)	1. RCT or cross over trials 2. HI individuals 3. comparison of 2 or more HA technologies 4. Either an objective laboratory test or a self-report QoF questionnaire	1. Laboratory test: no difference 2. Self-report: benefit of digital, but not consistent within or across studies 3. The evidence-base is small and of relatively poor quality (randomization described in 0 study; assessor blinded in 0 study)	+
Bergeron, 2003 [38]	Efficacy of directional-microphone HA vs omnidirectonial HA	24 (17 studies from electronic databases search + 19 studies from experts	-Clinical trials of directional HA - written in French or English - between 1990-2002	1. Most of the studies report on directionality with 2 microphones (single micro and multi-micro are considered "experimental approach" 2. directional microphone offer speech-in-noise benefit in optimal listening situation (1.5 to 8.5 dB) 3. lower or no benefit in every day life 4. Intermediate or low quality evidence (some studies are randomized, but with low statistical power)	+/- 1. Only Medline and Cochrane 2. Search strategy incompletely reported 3. Validation of the search not reported 4. Selection of articles not reported 5. Interpretation of results not stratified by level of study quality
Bergeron, 2003 [57]	Efficacy of programmable analog HA (allowing advanced signal-processing such as dynamic compression and multi-channel) vs analog HA	10 (18 studies from electronic database + 19 studies from experts)	-Clinical trials of directional HA - written in French or English - between 1990-2002	1. Programmable HA improve speech-intelligibility performance and users' subjective impressions 3. Intermediate or low quality evidence	+/- 1. Only Medline and Cochrane 2. Search strategy incompletely reported 3. Validation of the search not reported

					4. Selection of articles not reported 5. Results not stratified by level of study quality
Bentler, 2005 [56]	Effectiveness of directional microphones and noise reduction schemes	9 (only 2 studies for noise reduction)	- Published in peer-reviewed journal - Blinded (single or double) - Self-report outcomes reported	1. Directional HA resulted in some benefit on the PHAB/APHAB subscale, but no difference for user preference or satisfaction 2. Lacking evidence for noise reduction 3. Low quality evidence (4/9 studies randomized; only 1 double blind)	+
Sorri, 2001 [58]	Outcome of non-invasive rehabilitation	5	- Adult population - Published since 1990 - Cross-over trial with at least 20 patients or RCT with at least 40 patients - Validated instruments for outcome measurements	1. Few good quality studies and heterogeneous outcomes 2. Small preference for NL HA, but no difference in objective parameters	+/- - Characteristics of studies presented but no formal quality appraisal
Arlinger, 2003 [55]	1.Non-linear vs linear 2. Digital vs analog 3. Directional vs omnidirectional	8 (628 subjects) 8 (410 subjects) 6 (282 subjects)	-Population : ≥19 years -Published in 1990-2002 -RCT or cross-over trial with at least 20 patients - Maximum drop-out 15%	1. NL HA: no difference in laboratory; better sound quality in daily life, over linear HA 2. Digital: no benefit over analogue 3. Directional microphone: better speech test and subjective benefit measurement, over omnidirectional	+ - only Medline

Quality appraisal of systematic reviews

Bentler, 2005 [56]	+	-	+/-	Comments
1. Research question is adequately formulated	x			
2. Search strategy is adequately described			x	Medline, ComDisDome, Cochrane Search strategy incompletely described (no bolean between keywords)
3. Procedure to select articles is adequately described	x			
4. Quality appraisal is adequately described	x			
5. Procedure for data extraction well explained		x		
6. The most important characteristics of the original studies are well described	x			
7. Clinical and statistical heterogeneity of the studies has been handled properly				NA
8. The statistical pooling has been done in a correct way				NA
Conclusion: 1. Directional HA resulted in some benefit on the PHAB/APHAB subscale, but no difference for user preference or satisfaction 2. Lacking evidence for noise reduction 3. Low quality evidence (4/9 studies randomized; only 1 double blind)				

Sorri, 2001 [58]	+	-	+/-	Comments
1. Research question is adequately formulated	x			
2. Search strategy is adequately described	x			Medline, Cochrane
3. Procedure to select articles is adequately described	x			
4. Quality appraisal is adequately described			x	Characteristics of studies presented but no formal quality appraisal
5. Procedure for data extraction well explained		x		
6. The most important characteristics of the original studies are well described	x			
7. Clinical and statistical heterogeneity of the studies has been handled properly				NA
8. The statistical pooling has been done in a correct way				NA
Conclusion: 1. Few good quality studies and heterogeneous outcomes 2. Small preference for NL HA, but no difference in objective parameters				

Arlinger, 2003 [55]	+	-	+/-	Comments
1. Research question is adequately formulated	x			
2. Search strategy is adequately described	x			Medline
3. Procedure to select articles is adequately described	x			
4. Quality appraisal is adequately described	x		x	
5. Procedure for data extraction well explained		x		
6. The most important characteristics of the original studies are well described	x			
7. Clinical and statistical heterogeneity of the studies has been handled properly				NA
8. The statistical pooling has been done in a correct way				NA
Conclusion: 1. NL HA: no difference in laboratory; better sound quality in daily life, over linear HA 2. Digital: no benefit over analogue 3. Directional microphone: better speech test and subjective benefit measurement, over omnidirectional				

Taylor, 2001 [59]	+	-	+/-	Comments
1. Research question is adequately formulated	x			
2. Search strategy is adequately described	x			
3. Procedure to select articles is adequately described	x			
4. Quality appraisal is adequately described	x			
5. Procedure for data extraction well explained	x			
6. The most important characteristics of the original studies are well described	x			
7. Clinical and statistical heterogeneity of the studies has been handled properly				NA
8. The statistical pooling has been done in a correct way				NA (inappropriate to pool the results, but detailed qualitative analysis
Conclusion: 1. Laboratory test: no difference 2. Self-report: benefit of digital, but not consistent within or across studies 3. The evidence-base is small and of relatively poor quality (randomization described in 0 study; assessor blinded in 0 study)				

Bergeron, 2003- Directional microphone [38]	+	-	+/-	Comments
1. Research question is adequately formulated	x			
2. Search strategy is adequately described	x			Medline, Cochrane
3. Procedure to select articles is adequately described		-		
4. Quality appraisal is adequately described	x		x	
5. Procedure for data extraction well explained		x		
6. The most important characteristics of the original studies are well described	x			
7. Clinical and statistical heterogeneity of the studies has been handled properly	x			
8. The statistical pooling has been done in a correct way				NA
Conclusion: 1. Most of the studies report on directionality with 2 microphones (single micro and multi-micro are considered "experimental approach" 2. directional microphone offer speech-in-noise benefit in optimal listening situation (1.5 to 8.5 dB) 3. lower or no benefit in every day life 4. Low quality evidence (all cross over design, some of which are randomized, but with low statistical power)				

Bergeron, 2003- programmable HA [57]	+	-	+/-	Comments
1. Research question is adequately formulated	x			
2. Search strategy is adequately described			x	
3. Procedure to select articles is adequately described		-		
4. Quality appraisal is adequately described	x			
5. Procedure for data extraction well explained		x		
6. The most important characteristics of the original studies are well described	x			
7. Clinical and statistical heterogeneity of the studies has been handled properly		x		
8. The statistical pooling has been done in a correct way		x		
Conclusion: Programmable analog hearing aids improve speech-intelligibility performance and users' subjective impressions. However the evidence-base is weak. Some of the studies suggest that such device could be provided to candidates faced with noisy environments or a wide variety of listening situations, and to those who have a reduced dynamic range				

APPENDIX TO CHAPTER 3 (ECONOMIC EVALUATION)

SEARCH STRATEGY

Date	06/02/2007
Database (name + access ; eg Medline OVID)	Embase
Date covered (segment)	1995-2007
Search Strategy (attention, for PubMed, check « Details »)	#1. 'hearing aid'/de AND [humans]/lim AND ([adult]/lim OR [aged]/lim) AND [embase]/lim AND [1995-2007]/py (926) #2. cost* (400,635) #3. econom* (352,231) #4. pharmacoeconomic* (37,398) #5. expenditure* (28,619) #6. reimbursement* (25,178) #7. #2 OR #3 OR #4 OR #5 OR #6 (672,750) #8. #1 AND #7 (54)
Note	

Date	13/02/2007
Database (name + access ; eg Medline OVID)	EconLit (Ovid Technologies)
Date covered (segment)	1969-01/2007
Search Strategy (attention, for PubMed, check « Details »)	Hearing (82)
Note	

Date	13/02/2007
Database (name + access ; eg Medline OVID)	HTA and NHS-EED (CRD Databases)
Date covered (segment)	1995-2007
Search Strategy (attention, for PubMed, check « Details »)	MeSH Hearing Aids EXPLODE 1 RESTRICT YR 1995 2007 (60)
Note	

Date	15/02/2007
Database (name + access ; eg Medline OVID)	ACP Journal Club (OVID)
Date covered (segment)	1991 to January/February 2007
Search Strategy (attention, for PubMed, check « Details »)	1 hearing aid$.mp. [mp=title, abstract, full text, keywords, caption text] (3) 2 cost$.mp. [mp=title, abstract, full text, keywords, caption text] (927) 3 econom$.mp. [mp=title, abstract, full text, keywords, caption text] (218) 4 pharmacoeconomic$.mp. [mp=title, abstract, full text, keywords, caption text] (2) 5 expenditure$.mp. [mp=title, abstract, full text, keywords, caption text] (30) 6 2 or 3 or 4 or 5 (1020) 7 1 and 6 (1) 8 limit 7 to yr="1995 - 2007" (0)
Note	

Date	15/02/2007
Database (name + access ; eg Medline OVID)	CINAHL (OVID)
Date covered (segment)	1982 to February Week 1 2007
Search Strategy (attention, for PubMed, check « Details »)	1 hearing aid$.mp. or Hearing Aids/ (2845) 2 cost$.mp. [mp=title, subject heading word, abstract, instrumentation] (40564) 3 econom$.mp. [mp=title, subject heading word, abstract, instrumentation] (15220) 4 pharmacoeconomic$.mp. [mp=title, subject heading word, abstract, instrumentation] (211) 5 expenditure$.mp. [mp=title, subject heading word, abstract, instrumentation] (2943) 6 2 or 3 or 4 or 5 (53239) 7 1 and 6 (72) 8 limit 7 to yr="1995 - 2007" (69) 9 limit 8 to (adult <19 to 44 years> or middle age <45 to 64 years> or aged <65 to 79 years> or "aged <80 and over>") (22)
Note	

Date	15/02/2007
Database (name + access ; eg Medline OVID)	Cochrane Database of Systematic Reviews (OVID)
Date covered (segment)	4th Quarter 2006
Search Strategy (attention, for PubMed, check « Details »)	1 hearing aid$.mp. [mp=title, abstract, full text, keywords, caption text] (22) 2 cost$.mp. [mp=title, abstract, full text, keywords, caption text] (2353) 3 econom$.mp. [mp=title, abstract, full text, keywords, caption text] (1131) 4 pharmacoeconomic$.mp. [mp=title, abstract, full text, keywords, caption text] (20) 5 expenditure$.mp. [mp=title, abstract, full text, keywords, caption text] (143) 6 2 or 3 or 4 or 5 (2629) 7 1 and 6 (14) 8 limit 7 to yr="1995 - 2007" (14)
Note	

Date	15/02/2007
Database (name + access ; eg Medline OVID)	Cochrane Central Register of Controlled Trials (OVID)
Date covered (segment)	1st Quarter 2007
Search Strategy (attention, for PubMed, check « Details »)	1 hearing aid$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] (188) 2 cost$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] (12114) 3 econom$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] (3408) 4 pharmacoeconomic$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] (427) 5 expenditure$.mp. [mp=title, original title, abstract, mesh headings, heading words, keyword] (1444)

	6 2 or 3 or 4 or 5 (14711) 7 1 and 6 (6) 8 limit 7 to yr="1995 - 2007" (6)
Note	

Date	15/02/2007
Database (name + access ; eg Medline OVID)	British Nursing Index (OVID)
Date covered (segment)	1994 to January 2007
Search Strategy (attention, for PubMed, check « Details »)	1 hearing aid$.mp. [mp=title, abstract, heading words] (26) 2 cost$.mp. [mp=title, abstract, heading words] (1173) 3 econom$.mp. [mp=title, abstract, heading words] (463) 4 pharmacoeconomic$.mp. [mp=title, abstract, heading words] (0) 5 expenditure$.mp. [mp=title, abstract, heading words] (28) 6 2 or 3 or 4 or 5 (1543) 7 1 and 6 (0)
Note	

Date	15/02/2007
Database (name + access ; eg Medline OVID)	Database of Abstracts of Reviews of Effects (OVID)
Date covered (segment)	1st Quarter 2007
Search Strategy (attention, for PubMed, check « Details »)	1 hearing aid$.mp. [mp=title, full text, keywords] (8) 2 cost$.mp. [mp=title, full text, keywords] (4343) 3 econom$.mp. [mp=title, full text, keywords] (486) 4 pharmacoeconomic$.mp. [mp=title, full text, keywords] (21) 5 expenditure$.mp. [mp=title, full text, keywords] (32) 6 2 or 3 or 4 or 5 (4357) 7 1 and 6 (6)
Note	

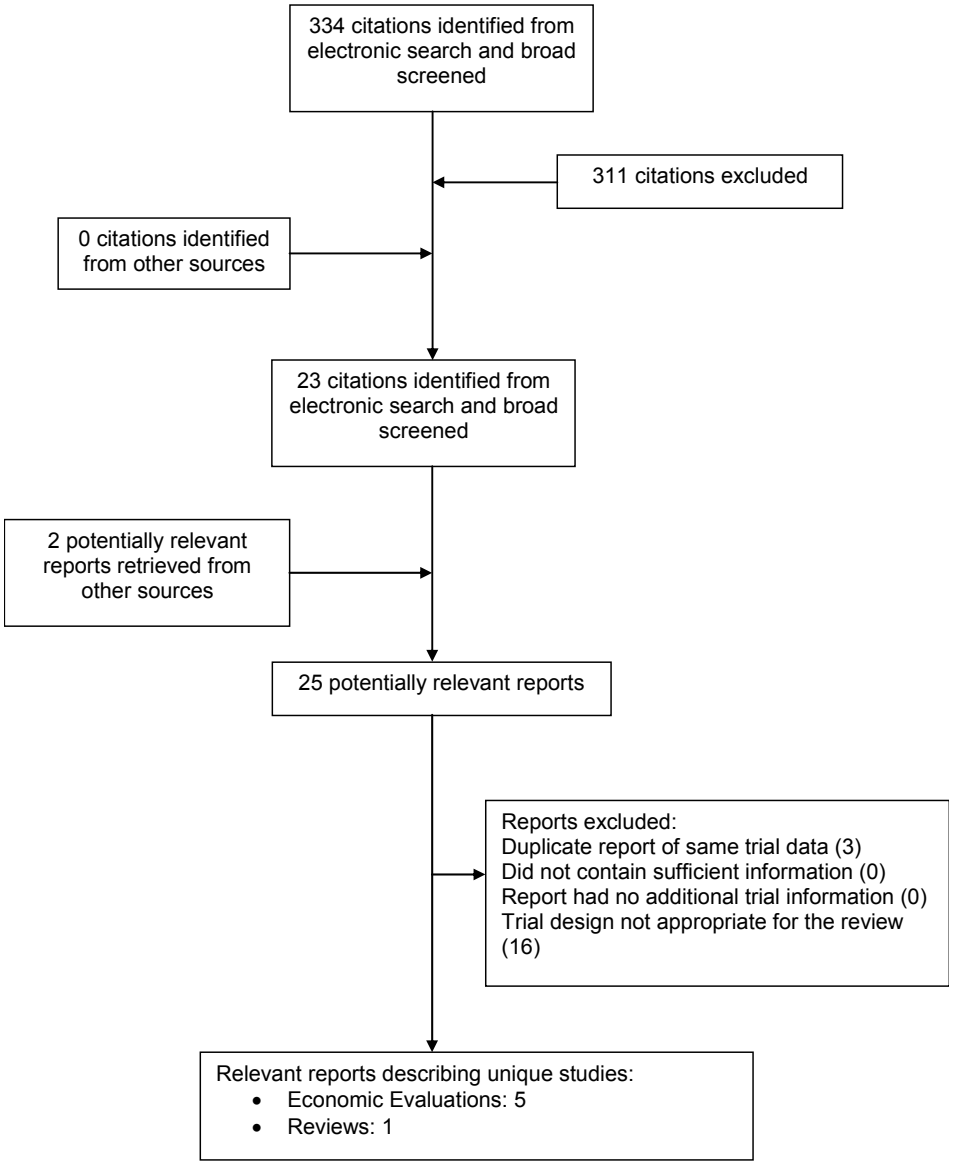
Date	15/02/2007
Database (name + access ; eg Medline OVID)	MEDLINE(R) (OVID)
Date covered (segment)	1950 to January Week 5 2007
Search Strategy (attention, for PubMed, check « Details »)	1 hearing aid$.mp. or Hearing Aids/ (6011) 2 cost$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (245021) 3 econom$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (130912) 4 pharmacoeconomic$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (1695) 5 expenditure$.mp. [mp=title, original title, abstract, name of substance word, subject heading word] (28820) 6 2 or 3 or 4 or 5 (359438) 7 1 and 6 (176) 8 limit 7 to yr="1995 - 2007" (103) 9 limit 8 to "all adult (19 plus years)" (49) 10 limit 9 to humans (49)
Note	

Date	13/02/2007
Database (name + access ; eg Medline OVID)	MEDLINE(R) In-Process & Other Non-Indexed Citations and MEDLINE(R) (OVID)
Date covered (segment)	1950 to Present
Search Strategy (attention, for PubMed, check « Details »)	1 hearing aid$.mp. [mp=ti, ot, ab, nm, hw] (6150) 2 cost$.mp. [mp=ti, ot, ab, nm, hw] (252065) 3 econom$.mp. [mp=ti, ot, ab, nm, hw] (134235) 4 pharmacoeconomic$.mp. [mp=ti, ot, ab, nm, hw] (1778) 5 expenditure$.mp. [mp=ti, ot, ab, nm, hw] (29431) 6 2 or 3 or 4 or 5 (369477) 7 1 and 6 (186) 8 limit 7 to yr="1995 - 2007" (113) 9 limit 8 to "all adult (19 plus years)" (49)
Note	

Date	08/03/2007
Database (name + access ; eg Medline OVID)	Pubmed
Date covered (segment)	1995 to Present
Search Strategy (attention, for PubMed, check « Details »)	"Hearing Aids"[MeSH] AND ("Costs and Cost Analysis"[MeSH] OR "Economics"[MeSH] OR "economics"[Subheading] OR "Cost-Benefit Analysis"[MeSH] OR "Cost Allocation"[MeSH] OR "Cost of Illness"[MeSH] OR "Cost Control"[MeSH] OR "Cost Sharing"[MeSH] OR "Cost Savings"[MeSH] OR "Technology, High-Cost"[MeSH] OR "Health Care Costs"[MeSH] OR "Direct Service Costs"[MeSH] OR "Hospital Costs"[MeSH]) (134)
Note	

FLOW CHART OF LITERATURE RETRIEVAL

Figure 42: Flow chart of literature retrieval cost-effectiveness.



DATA EXTRACTION FORMS

Authors (Year)	Abrams H, Chisholm TH, McArdle R. 2002
Funding	Rehabilitation Research and Development Service. Department of Veterans Affairs
Country	USA
Design	CUA - Randomized Clinical Trial
Perspective	Not specified
Time window	Not clear : cost : +/- 4 weeks and QALYs : lifelong (data collection over 2 years : 1999-2001)
Interventions	(P1) HA fitting versus before HA fitting (n= 52). (P2) HA use along with short-term group post fitting AR versus before HA fitting (n = 53). AR = 2-hour group meeting once a week for 4 weeks). HA studied: Starkey programmable hearing aids.
Population	105 veterans (% males: 63,8%) with acquired hearing loss and were eligible to receive HA. Inclusion criteria: at least a mild sensorineural hearing loss in the better ear (four frequency pure tone average of ≥ 30db HL at 500, 1000, 2000 and 4000 Hz), no prior HA experience, no more than mild depression on the beck Depression Inventory and no known neurological, neuromuscular, psychiatric or visual disorder.
Assumptions	Conservative assumption : gain in cost due to reduced visits for HA modifications and to reduced returns and reorders were not included
Data source for costs	Not specified
Cost items included	Direct costs (labour, supplies and materials, equipment, transportation) and indirect costs (administration, building maintenance, …)
Data source for outcomes	This randomized clinical trial. QALY = [Sum(L*DM)]/n ; L = Life expectancy from gender specific actuarial tables,[132] DM = change score on SF-36V mental component summary scale and n = number of patients
Discounting	NA
Costs	HA : $ 1,056.73 / HA + AR : $ 1,119.43
Outcomes	(P1) : mean mental component summary (MCS) scale scores change = 1.4 points (P2) : mean MCS scale scores change = 3.0 points / ANOVA : differences in treatment effect between the groups were not significant / QALYs and average further life expectancy were not specified.
Cost-effectiveness	(P1) : $60/QALY (P2) : $31,91/QALY
Sensitivity analysis	Not performed
Conclusions	(P2) is more cost-effective than (P1)

Remarks	1) Gains in QALY were not specified. 2) QALYs were estimated from mental component and thus did not consider all aspects of quality of life. 3) Incertitude was not tested with sensitivity analysis or confidence intervals. 4) Productivity loss was not assessed but was not necessary because veterans are unlikely to be economically active. 5) We can easily assume that the type of HA studied has a significant influence on the effect of a counselling program. Because the impact of HA characteristics was not taken into account in this study, we considered that alternatives compared were not relevant and that the present study does not allow us to make valid conclusions about the utility of a counselling program.

Authors (Year)	Boas G, van der Stel H, Peters H, Joore M, Anteunis L. 2001
Funding	European Hearing Instrument Manufacturers Association (EHIMA) and the Maastricht Ear, Nose and Throat (ENT) Research Foundation
Country	Netherlands
Design	CUA - Modelling study (annual cycle)
Perspective	Societal
Time window	Lifelong (follow-up measurement = 16 weeks)
Interventions	(P1) Fitting HA program: HA fitting versus before HA fitting (P2) Post-purchase Counselling HA program: HA fitting + counselling versus before HA fitting. HA studied were not described.
Population	Patients aged 18 years and older with hearing complaints living in Netherlands. Inclusion criteria: pure tone average of ≥ 35db HL at 1, 2 and 4 kHz and with no prior HA experience.
Assumptions	1) The development of hearing complaints is irreversible. 2) The prevalence of a dissatisfied attitude toward HA use is higher in first-time user than in reapplicants (= with HA experience). 3) Transitions take place during the year. 4) Benefits are only counted for satisfied HA. No benefit is taken into account for dissatisfied HA users. 5) Age differences within a cohort are small enough to consider that these subgroups have homogenous transition probabilities. 6) Transition probabilities and costs are constant over time. 7) The extra cost of counselling was €37 per first-time user and there was 36% fewer dissatisfied HA users due to counselling.
Data source for costs	A clinical study of the SIHI group (Tariffs; a description of this study is given below).[87-89] Cost of counselling: Ward 1993.[133]
Cost items included	Health care intervention costs. (Transportation and productivity loss not included).
Data source for outcomes	A clinical study of the SIHI group,[87, 88] and demographic forecasts [134] / Effect of counselling : Ward 1993. [133]
Discounting	Costs : 5% / Outcomes : 5%
Costs	Not specified
Outcomes	Not specified

Cost-effectiveness	For the age group of 60-64 years old: Fitting HA program: € 21,154/QALY. 2) Post-purchase Counselling HA program: € 18,046/QALY
Sensitivity analysis	Performed on the price of HA, on utility values, on the number of binaural fittings and on the ratio male/female. Results are sensitive to the price of HA and to utility values. Results are better for female than for male due to difference in mortality rate.
Conclusions	ICER is better for the Post-purchase Counselling HA program and ICER of the two hearing aid programs are better in younger age group than in older age group.
Remarks	1) The main aim of the study was to develop a dynamic model to perform economic evaluation and not to achieve a detailed economic evaluation. 2) Sensitivity analysis did not take into account all key parameters (i.e. extra cost and effect of counselling). 3) Productivity loss was not assessed but was not necessary. Indeed, most persons requiring HA are unlikely to be economically active. 4) We can easily assume that the type of HA studied has a significant influence on the effect of a counselling program. Because the impact of HA characteristics was not taking into account in this study, we considered that alternatives compared were not relevant and that study did not allow us to make conclusion about the utility of a counselling program. 5) It should also be noticed that, according to the sources for outcomes measure,[87, 88] the effect of HA fitting on the generic quality of life was not significant. Thus, Boas' findings are not significant.

Authors (Year)	Joore M, van der Stel H, Peter H, Boas G, Anteunis L. 2003
Funding	European Hearing Instrument Manufacturers Association (EHIMA), the Heinsius-Houbolt Foundation and the Maastricht Ear, Nose and Throat (ENT) Research Foundation
Country	Netherlands
Design	CUA - Modelling study (annual cycle)
Perspective	Societal
Time window	Lifelong (follow-up measurement = 4 months)
Interventions	HA fitting versus before HA fitting. Characteristics of HA studied were not detailed (79% were fitted with a HA behind the ear).
Population	Adult patients with hearing complaints (pure tone average of ≥ 35db HL at 1, 2 and 4 kHz), with no prior HA experience and without contraindications for HA use.
Assumptions	1) If the person was not satisfied with the fit of the HA, no HA would be purchased. 2) Among dissatisfied HA users, 90% were 60 years and older 3) Every person who receives a prescription sees a dispenser. 4) Benefits are only counted for satisfied HA. No benefit is taken into account for dissatisfied HA users.
Data source for costs	Charge information, consumer information, Nederlandse Vereniging van Audiciens Bedrijven (NVAB) information + Dutch reports.[135-139]
Cost items included	Direct health care intervention costs: consultations, diagnostics, HA fitting, HA instrument and HA use (batteries and repairs). Saving due to gain in productivity after HA fitting. Direct non-health care costs (i.e. transportation cost) were not included.
Data source for outcomes	Utilities : this study / Transition probabilities : expert opinion + literature.[138, 140-144]
Discounting	Costs : 5% / Outcomes : 5%

Costs	Average incremental cost of HA fitting : €781 (worst case : €1,197, best case : €490)
Outcomes	Incremental QALY : 1) Based on the EQ-5D population utility estimate : on average 0.05 QALYs gained (difference not significant) 2) Based on the EQ-5D VAS: on average 0.03 QALYs gained. 3) Based on the hearing-specific VAS : on average 0.44 hearing-QALYs gained
Cost-effectiveness	1) Based on the EQ-5D population utility estimate : on average €15,807/QALY (youngest : €11,984/QALY; oldest : €34,902/QALY) 2) Based on the EQ-5D VAS: on average €23,745/QALY (youngest: €17,996/QALY; oldest: €52,502/QALY). 3) Based on the hearing-specific VAS : on average €1,759/hearing-QALY (youngest: €1,333/hearing-QALY; oldest: €3,889/hearing-QALY)
Sensitivity analysis	Performed on the price of HA, on utility values, on the number of binaural fittings, the replacement time of a HA, the chance of becoming dissatisfied and others key parameters of the model. Results are sensitive to the price of HA, to the probability to become dissatisfied and especially to utilities. Concerning change in utilities, HA lead to higher cost and lower QALYs than without HA in the worst-case scenario.
Conclusions	Regarding the base case scenario, fitting of hearing aids is a cost-effective health care intervention. However, the CI of the ICER includes negative values (higher costs for lower QALY) because the effect of HA fitting on generic quality of life was not significant.
Remarks	Because no effect on generic quality of life was demonstrated as significant, we can not conclude that HA fitting is a cost-effective health care intervention. Moreover, comparison between HA should be done to determine which type of HA gives better ICER.

Authors (Year)	Newman CW, Sandridge SA, The Cleveland Clinic Foundation, OH. 1998
Funding	American Speech-Language-Hearing Foundation (ASHF)
Country	USA
Design	CEA - Prospective clinical trial
Perspective	Not specified
Time window	at least 4-week period for each HA
Interventions	(HA-A) = A one-channel linear conventional analogue HA (HA-B) = a 2-channel non-linear HA (HA-B) (HA-C) = a 7-band 2-channel digital signal processing HA (HA-C). (HA versus without HA and HA comparisons)
Population	Twenty-five conventional HA users aged at least 21 years with adult onset of sensorineural hearing loss, with at least 1 year of continuous HA experience, without conductive or fluctuating sensorineural hearing loss, without previous history of neurologic or psychiatric disorders, able to read and comprehend a simple passage and with normal cognitive function.
Assumptions	/
Data source for costs	Retail purchase price
Cost items included	HA purchase price
Data source for outcomes	This prospective clinical trial
Discounting	Costs : 5% / Outcomes : 5%
Costs	HA-A : $1,192 / HA-B : $1,660 / HA-C : $3,732.

Outcomes	1) There were no significant differences between the three HA technologies in terms of : ▪ mean audibility index (AI) for the 50 dB HL input level ▪ satisfaction with sound quality features (SQ-Sat) and listening conditions (LC-Sat) ▪ benefit scores from the APHAB or the HHIE questionnaires 2) HA-C had significantly higher scores than HA-A with the Speech and Noise (Spin) test 3) HA-A had significantly higher mean AIs for the 80dB HL input level than HA-C 4) Benefit scores with the SPIN-LP : ▪ HA-A versus no HA : 24 ▪ HA-B versus no HA : 32 ▪ HA-C versus no HA : 34 5) Benefit scores with the HHIE/A : ▪ HA-A versus no HA : 12.1 ▪ HA-B versus no HA : 14.8 ▪ HA-C versus no HA : 16.7
Cost-effectiveness	1) With the SPIN-LP : ▪ HA-A versus no HA : $49.67 ▪ HA-B versus no HA : $51.88 ▪ HA-C versus no HA : $109.76 ▪ HA-B versus HA-A : $58.50 ▪ HA-C versus HA-A : $254 ▪ HA-C versus HA-B : $1,036 2) With the HHIE/A : ▪ HA-A versus no HA : $98.51 ▪ HA-B versus no HA : $112.16 ▪ HA-C versus no HA : $223.47 ▪ HA-B versus HA-A : $173,33 ▪ HA-C versus HA-A : $552.17 ▪ HA-C versus HA-B : $1,090.53
Sensitivity analysis	Not performed
Conclusions	HA-A is the most cost-effective intervention. Because HA-B provides improved benefit for marginal increase in cost, it could be argued that HA-B is the most cost-effective among the test instruments.
Remarks	1) Uncertainty was not handled (Confidence interval for the ICER was not given) 2) Because differences in outcomes between the three HA technologies were not significant for almost all the tests, it is not correct to conclude that HA-B is the most cost-effective among the test instruments. 3) Effect of HAs on generic quality of life was not measured. 4) Costs were only analysed by HA purchase price. 5) The comparators' choice was clear and justified in the context of the study but may not be relevant in other settings.

Authors (Year)	Vuorialho A, Karinen P, Sorri M. 2006
Funding	Not specified
Country	Finland
Design	CEA - prospective clinical trial
Perspective	Not specified
Time window	1 year
Interventions	(P1) = HA fitting (6 months) versus before HA fitting. (P2) = HA fitting (12 months) with counselling (6 months) versus before HA fitting. (P3) = HA fitting (12 months) with counselling (6 months) versus HA fitting (6 months). Follow-up counselling was performed 6 months after fitting. HA were fitted monaurally. Characteristics of HA studied: 51.0% were digital signal processing type (DSP Has), 45.9% were analogue HAs and for 3.1%, information was not available.
Population	98 patients who visited the Kainuu Central Hospital and with no prior HA experience. Median age 76.7 (range: 47-87); Presbiacusis : 73.5%; moderate hearing impairment : 86.7%.
Assumptions	/
Data source for costs	This prospective clinical trial (hospital records).
Cost items included	Direct cost of follow-up counselling: part-time audiology assistant's salary and travel costs.
Data source for outcomes	This prospective clinical trial
Discounting	NA
Costs	Unit cost of follow-up counselling: €83/visit. Total follow-up counselling cost : €8,134
Outcomes	1) Change in HHIE score: (P1) significant (P2) significant (P3) not significant. 2) Improvement in the EQ-5D index: (P1) not significant (P2) not significant (P3) not significant. 3) Improvement in the EQ-5D VAS : (P1) significant (P2) not significant (P3) not significant 4) Increase in HA regular users due to counselling (P3): 16 patients (significant).
Cost-effectiveness	HA + counselling versus HA (P3) : €508 per one additional regular user
Sensitivity analysis	Not performed
Conclusions	Counselling can significantly increase HA use and the consequent benefit at an acceptable cost.
Remarks	1) Uncertainty was not handled (Confidence interval for the ICER was not given). 2) Effect of counselling on hearing-related and generic quality of life was not significant. It is thus wrong to conclude that benefits due to a better HA use increased through counselling. 3) We can easily assume that the type of HA studied has a significant influence on the effect of a counselling program. Because the impact of HA characteristics was not taking into account in this study, we considered that alternatives compared were not relevant and that study did not allow us to make conclusion about the utility of a counselling program.
Authors (Year)	Societal Impact of Hearing Impairment study group (SIHI)

Funding	Maastricht Health Economics Research and Consultancy Agency (MHERCA)
Country	Netherlands
Design	CUA - Modeling study (annual cycle)
Perspective	Not clearly specified (societal?)
Time window	16 weeks
Interventions	Fitting HA program: HA fitting versus before HA fitting. HA studied were not described.
Population	66 patients aged 18 years and older with hearing complaints living in Netherlands (mean age: 68.59, % male: 56.1%, Fletcher Index best ear: 47.55). Inclusion criteria: patients who received a prescription for a hearing aid for the first time (first-time HA user) and who visited the ENT clinic of the Maastricht Hospital or the Audiological Centre Hoensbroeck, patients who were mentally able to performed the study and to speak and understand Dutch.
Assumptions	/
Data source for costs	Tariffs of the ENT clinic and audiology clinic
Cost items included	Health care intervention costs. (Transportation and productivity loss not included)
Data source for outcomes	This clinical study
Discounting	Costs : 5% / Outcomes : 5%
Costs	Not found (they explained that details were given in appendix but appendix were not found)
Outcomes	Utility gain: 1) with the EuroQoL: 4% 2) with the Hearing QoL: CI 95%: 17-21%
Cost-effectiveness	For the age group of 65-69 years old: 1) with the EuroQoL: € 11,500/QALY 2) with the Hearing QoL : €2,200/QALY-€2,700/QALY
Sensitivity analysis	Not performed
Conclusions	This program should be adopted (< €20.000)
Remarks	1) Parameters of the model were not detailed (i.e. transition probabilities). 2) Sensitivity analysis was not performed. 3) Details on cost data were not found. 4) Comparison between HA should be done to determine which type of HA gives better ICER.

QUALITY ASSESSMENT CHECKLIST

Study design	Abrams	Boas	Joore	Newman	Vuorialho	SIHI
The research question is stated	Yes	NA	Yes	Yes	Not clearly	Partially
The economic importance of the research question is stated	Yes	Yes	Yes	Yes	Yes	Yes
The viewpoints of the analysis are clearly stated and justified	No	Yes	Yes	No	No	No
The rationale for choosing the alternative programmes or interventions compared is stated	Yes	No	No	Yes	No	No
The alternatives being compared are clearly described	Partially	No	No	Yes	No	No
The form of economic evaluation used is stated	Yes	No	No	Yes	Yes	No
The choice of form of economic evaluation is justified in relation to the questions addressed	Yes	Yes	Yes	No	No	Yes

Data collection	Abrams	Boas	Joore	Newman	Vuorialho	SIHI
The sources of effectiveness estimates used are stated	Yes	Yes	Yes	Yes	Yes	Yes
Details of the design and results of effectiveness study are given (if based on a single study)	Partially	No	No	Yes	Yes	Partially
Details of the method of synthesis or meta-analysis of estimates are given (if based on an overview of a number of effectiveness studies)	NA	NA	NA	NA	NA	NA
The primary outcome measure(s) for the economic evaluation are clearly stated	Yes	Yes	Yes	Yes	Yes	Yes
Methods to value health states and other benefits are stated	Yes	Sources are given	Yes	Yes	Yes	Yes
Details of the subjects from whom evaluations were obtained are given	Yes	No	Partially	Partially	Yes	Yes
Productivity changes (if included) are reported separately	NA	NA	Yes	NA	NA	NA
The relevance of productivity changes to the study question is discussed	No	Yes	NA	No	No	No

Quantities of resources are reported separately from their unit costs	No	Done but not reported	Partially	No	No	Done but details not found
Methods for the estimation of quantities and unit costs are described	No	Sources are given	Sources are given	Yes	Yes	Yes
Currency and price data are recorded	No (price year not reported)	No (price year not reported)	Yes	No (price year not reported)	No (price year not reported)	No (price year not reported)
Details of currency or price adjustments for inflation or currency conversion are given	No	No	Yes	No	NA	Yes
Details of any model used are given	NA	Yes	Yes	NA	NA	No
The choice of model used and the key parameters on which it is based are justified	NA	Sources are given	Yes	NA	NA	No
Analysis and interpretation of results	**Abrams**	**Boas**	**Joore**	**Newman**	**Vuorialho**	**SIHI**
Time horizon of costs and benefits is stated	Not clear	Yes	Yes	Not clear	Yes	Yes
The discount rate(s) is stated	NA	Yes	Yes	NA	NA	Yes
The choice of rate(s) is justified	NA	No	No	NA	NA	No
An explanation is given if costs or benefits are not discounted	No	NA	NA	No	No	NA
Details of statistical tests and confidence intervals are given for stochastic data	No	NA	Yes	No	Partially	No
The approach to sensitivity analysis is given	NA	Yes	Yes	No	NA	No
The choice of variables for sensitivity analysis is justified	NA	No	Yes	NA	NA	NA
The ranges over which the variables are varied are stated	NA	Yes	Yes	NA	NA	NA
Relevant alternatives are compared	No	No	No	Yes	No	No
Incremental analysis is reported	No	Yes	Yes	Yes	Yes	Yes
Major outcomes are presented in a disaggregated as well as aggregated form	No	No	Yes	Yes	Yes	No
The answer to the study question is given	No	No	Partially	No	No	No
Conclusion follow from the data reported	Yes	Yes	Yes	No	No	Yes
Conclusions are accompanied by the appropriate caveats	No	No	Yes	No	No	No

APPENDIX TO CHAPTER 4 (HEARING AIDS INVENTORY)

HEARING AIDS COMPARISON

Table 38: Veranneman - Hearing aids comparison.

Supplier	Veranneman	Veranneman	Veranneman	Veranneman	Veranneman	Veranneman	Veranneman	Veranneman
Brand	WIDEX	WIDEX	WIDEX	WIDEX	WIDEX	SIEMENS	SIEMENS	SIEMENS
Hearing aid	B2	DIVA	Inteo IN-19	Bravissimo BV9vc	Senso Vita 9	Acuris Life (open)	Lotus 13P	Cielo directionnel
Price	780 euros	1580 euros	1980 euros	1050 Euros	1450 Euros	1750 euros	500 euros	1450 euros
S= used in the study; MB = most sold; MC = Most sold in centers	MC	MC	MC	MB	MB	MB	S MB	S
Analogic	No	No	No	No	No	No	No	No
Partially digital	No	No	No	No	No	No	No	No
Full digital	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Linear amplification	No	No	No	No	No	No	Yes	No
No linear amplification	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
Potentiometer	No	No		Yes	Yes	No	Yes	Yes
Full automatic	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
Microphone: directional	No	Yes	Yes	Yes	Yes	Yes	No	Yes
Micro: omnidirectional	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Micro: partially directional	No	Yes		No	No	Yes	No	No
Micro : fixed directionability	No	Yes		No	Yes	No	No	No
Micro: adaptative directionability	No	Yes	Yes	No	No	Yes	No	Yes
Micro :adaptative directionability multibands	No	No	Yes	No	No	Yes	No	
Noise reduction	No	Yes	Yes	No	Yes	Yes	No	Yes
Voice enhancement	No	Yes	Yes	No	Yes	Yes	No	Yes
Feedback reduction (static)	Yes	No	No	Yes	Yes	No	No	Yes

Supplier	Veranneman	Veranneman	Veranneman	Veranneman	Veranneman	Veranneman	Veranneman	Veranneman
Brand	WIDEX	WIDEX	WIDEX	WIDEX	WIDEX	SIEMENS	SIEMENS	SIEMENS
Hearing aid	B2	DIVA	Inteo IN-19	Bravissimo BV9vc	Senso Vita 9	Acuris Life (open)	Lotus 13P	Cielo directionnel
Price	780 euros	1580 euros	1980 euros	1050 Euros	1450 Euros	1750 euros	500 euros	1450 euros
FB reduction without gain reduction (dynamic, adaptative)	No	Yes	Yes	No	No	Yes	No	No
Frequency range			100- 6800 Hz	175- 7100 Hz	?	130-6300	160-5200	100-6700 Hz
Averaged max output 90dB(2 cc coupler)	109dB	113 dB	124 dBSPL	111 dB SPL	116 dBSPL	119 dB	128 dB	124 dB
Harmonic distortion 500 Hz	1%??	1%??	1.8%	1.7%	2.1%	1%	4%	3%
Harmonic distortion 800 Hz			0.6%	0.4%	0.7%	2%	3%	2%
Harmonic distortion 1600 Hz			0.1%	0.2%	0.7%	2%	1%	1%
Equivalent input noise	32 kHz/20 bits	32kHz/20bit	23 dBSPL	34 dBSPL	~0	18 dB	16dB	16 dB
Channels nb	2	15		3	3	16	1	6
Channels with adjustable compression	2	15	3	3	3	4	1	3
AGC-O	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Nb of individual programs		3		1	2	1	1	3
Environment memory	No		3	No	No	Yes	No	No
Environment automatic adaptation (data learning)	No		Yes	No	No	No	No	No
Environment manual adaptation	No			No	No	No	No	No
Induction coil	Yes			Yes	Yes	Yes	Yes	Yes
Audio input	Yes		Yes	Yes	Yes	No	Yes	Yes
M-T (second micro to allow M and T together)	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
Automatic coil detection	No		Yes	No	No	No	No	Yes
Audioautomatic detection of audio input	No			No	Yes	No	No	Yes
Battery current drain	0.7mA	1.25 mA	0.75 mA	0.6 mA	0.75 mA	1 mA	1mA	1.2 mA

Supplier	Veranneman	Veranneman	Veranneman	Veranneman	Veranneman	Veranneman	Veranneman	Veranneman
Brand	WIDEX	WIDEX	WIDEX	WIDEX	WIDEX	SIEMENS	SIEMENS	SIEMENS
Hearing aid	B2	DIVA	Inteo IN-19	Bravissimo BV9vc	Senso Vita 9	Acuris Life (open)	Lotus 13P	Cielo directionnel
Price	780 euros	1580 euros	1980 euros	1050 Euros	1450 Euros	1750 euros	500 euros	1450 euros
Battery life	375H	215H	285H	450 H	350H	120H	220H	190H
Battery control	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Reduction of HF interferences (GSM, mobile phone)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Optimized solution for binaural fitting	No			No	No	Yes	No	No
Wireless	No			No	No	Yes	No	No
Music detection and adaptation	No	Yes		No	No	No	No	No
Wind noise reduction	No			No	No	Yes	No	Yes

Table 39: Lapperre - Hearing aids comparison.

Supplier	Lapperre	Lapperre	Lapperre	Lapperre	Lapperre	Lapperre	Lapperre
Brand	PHONAK	LAPPERRE	LAPPERRE	PHONAK	PHONAK	OTICON	OTICON
Hearing aid	Savia Art 211	Eterna 211	Lapperre 1400	Extra	Maxx 211 D	Swift 70+	Tego
Price	2250 euros	1900 euros	1300 euros	1375 euros	1300 euros	500 euros	1275 euros
S= used in the study; MB = most sold; MC = Most sold in centers	MB MC	MB	MB	MB	MB	S MC	S MC
Analogic	No	No	No	No	No	Yes	No
Partially digital	No	No	No	No	No	Yes	No
Full digital	Yes	Yes	Yes	Yes	Yes	No	Yes
Linear amplification	No	Yes	No	Yes	No	Yes	No
No linear amplification	Yes	Yes	Yes	Yes	Yes	No	Yes
Potentiometer	Yes	Yes	No	Yes	Yes	Yes	No
Full automatic	Yes	Yes	Yes	Yes	Yes	No	Yes
Microphone: directional	Yes	Yes	Yes	Yes	No	No	Yes
Micro: omnidirectional	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Micro: partially directional	No	No	Yes	No	No	No	No
Micro : fixed directionability	No	No	Yes	Yes	No	No	Yes
Micro: adaptative directionability	Yes	Yes	No	No	No	No	No
Micro :adaptative directionability multibands	Yes	No	No	No	No	No	No
Noise reduction	Yes	Yes	Yes	Yes	Yes	No	Yes
Voice enhancement	No	No	No	No	No	No	No
Feedback reduction (static)	No	No	No	No	Yes	No	No
FB reduction without gain reduction (dynamic, adaptative)	Yes	Yes	Yes	Yes	No	No	Yes
Frequency range	<100-6800	<100-6800	170-5900	<100-6800	<100-4700 Hz	100-6200	140-5800
Averaged max output 90dB(2 cc coupler)	128	128	112	128	125	124	120
Harmonic distortion 500 Hz	2%	2%	0.5%	2%	1%	0.5%	0.5%
Harmonic distortion 800 Hz	1%	1%	0.5%	1%	0.5%	0.5%	0.5%

Supplier	Lapperre	Lapperre	Lapperre	Lapperre	Lapperre	Lapperre	Lapperre
Brand	PHONAK	LAPPERRE	LAPPERRE	PHONAK	PHONAK	OTICON	OTICON
Hearing aid	Savia Art 211	Eterna 211	Lapperre 1400	Extra	Maxx 211 D	Swift 70+	Tego
Price	2250 euros	1900 euros	1300 euros	1375 euros	1300 euros	500 euros	1275 euros
Harmonic distortion 1600 Hz	1%	1%	0.5%	1%	0.5%	0.5%	0.5%
Equivalent input noise	19 dB SPL	19 dB SPL	16 dB SPL	19dB SPL	21 dB SPL	22	20
Channels nb	20	16	4	6	6	1	4
Channels with adjustable compression	20	16	4	6	6	1	4
AGC-O	Yes	Yes	Yes	Yes	Yes	No	Yes
Nb of individual programs	4	3	1	2	1	1	3
Environment memory	Yes	Yes	No	Yes	No	No	No
Environment automatic adaptation (data learning)	Yes	No	No	No	No	No	No
Environment manual adaptation	Yes	Yes	No	No	No	No	No
Induction coil	Yes	Yes	Yes	Yes	Yes	No	Yes
Audio input	Yes	Yes	Yes	Yes	Yes	No	Yes
M-T (second micro to allow M and T together)	Yes	Yes	Yes	Yes	Yes	No	No
Automatic coil detection	Yes	Yes	No	Yes	No	No	Yes
Audioautomatic detection of audio input	Yes	Yes	No	No	No	No	No
Battery current drain	1.1 mA	1.1 mA	1.1 mA	0.9 mA	0.65 mA	0.8mA	1.1mA
Battery life	250 h	250 h	250 h	300 h	450 h	280H	220H
Battery control	Yes	Yes	Yes	Yes	Yes		
Reduction of HF interferences (GSM, mobile phone)	Yes	Yes	Yes	Yes	Yes	No	Yes
Optimized solution for binaural fitting	No	No	No	No	No	No	No
Wireless	No	No	No	No	No	No	Yes
Music detection and adaptation	Yes	No	No	No	No	No	No
Wind noise reduction	Yes	No	No	No	No	No	No

Table 40: Dialogue Gn ReSound - Hearing aids comparison.

Supplier	Gn ReSound	Gn ReSound	Gn ReSound	Gn ReSound	Gn ReSound
Brand	Gn ReSound	Gn ReSound	Gn ReSound	Gn ReSound	Gn ReSound
Hearing aid	Canta 270	ReSound + 5	Discover V	Metrix 70 DVI	Pulse
Price	975 euros	1475 euros	500 euros	2095 euros	1875 euros
S= used in the study; MB = most sold; MC = Most sold in centers	MB	S MB MC	S	MC	MC
Analogic	No	No	No	No	No
Partially digital	No	No	No	No	No
Full digital	Yes	Yes	Yes	Yes	Yes
Linear amplification	No	No	Yes	No	No
No linear amplification	Yes	Yes	No	Yes	Yes
Potentiometer	No	Yes	Yes	Yes	No
Full automatic	Yes	Yes	Yes	Yes	Yes
Microphone: directional	No	Yes	No	Yes	Yes
Micro: omnidirectional	Yes	Yes	Yes	Yes	No
Micro: partially directional	No	No	No	No	No
Micro : fixed directionability	No	Yes	No	No	Yes
Micro: adaptative directionability	No	No	No	Yes	No
Micro :adaptative directionability multibands	No	No	No	Yes	No
Noise reduction	No	Yes	No	Yes	Yes
Voice enhancement	No	No	No	Yes	Yes
Feedback reduction (static)	No	No	No	No	No
FB reduction without gain reduction (dynamic, adaptative)	Yes	Yes	No	Yes	Yes
Frequency range	100-5300	100-5590Hz	160-6000		100-6840
Averaged max output 90dB(2 cc coupler)	123 dB	125	126		107 dB
Harmonic distortion 500 Hz					0.5%
Harmonic distortion 800 Hz	1%	0.5%	0.5%		0.1%
Harmonic distortion 1600 Hz	1%	0.4%	0.3%		0.4%
Equivalent input noise	26	28			27 dB
Channels nb	6	6	4	17	

Supplier	Gn ReSound	Gn ReSound	Gn ReSound	Gn ReSound	Gn ReSound
Brand	Gn ReSound	Gn ReSound	Gn ReSound	Gn ReSound	Gn ReSound
Hearing aid	Canta 270	ReSound + 5	Discover V	Metrix 70 DVI	Pulse
Price	975 euros	1475 euros	500 euros	2095 euros	1875 euros
Channels with adjustable compression	6	6	4	17	
AGC-O	Yes	Yes	Yes	Yes	Yes
Nb of individual programs	2	2	1	2	1
Environment memory	No	Yes	No	Yes	Yes
Environment automatic adaptation (data learning)	No	No	No	No	No
Environment manual adaptation	No	Yes	No	Yes	Yes
Induction coil	Yes	Yes	Yes	Yes	Yes
Audio input	Yes	Yes	No	Yes	Yes
M-T (second micro to allow M and T together)	Yes	Yes	No	Yes	No
Automatic coil detection	No	No	No	No	No
Audioautomatic detection of audio input	No	No	No	No	No
Battery current drain	1.1 mA	1.26 mA	1.2 mA		
Battery life	235H	230H	217H		
Battery control	Yes	Yes	Yes	Yes	Yes
Reduction of HF interferences (GSM, mobile phone)	Yes	Yes	Yes	Yes	Yes
Optimized solution for binaural fitting					
Wireless	No	No	No	No	No
Music detection and adaptation	No	No	No	Yes	No
Wind noise reduction	No	No	No	Yes	Yes

DETAILED HA INVENTORY

PHONAK

17 Hearing aids types

91 Hearing aids subtypes

High prices	44	48%
Middle prices	27	31%
Low prices	20	21%

Line of goods

Types	**Subtypes**	**Price Phonak (€)**	**Price Lapperre (€)**
Savia Art	11RC	2200	2250
	22**	**2200****	2250
	22dSZ	2200	
	33**	**2200****	
	33dSZ**	**2200****	
	33 P**	**2200****	
	211 ART Dsz	**2200****	2250
	311 ART Dsz**	**2200****	
	411 ART Dsz**	**2200****	
Micro Savia ART	100 dSZ	2350	2400
	CRT dSZ	2350	2400
Micro POWER	IX	2350	
	V	1900	
	III	1425	
Eleva	11 RC	1800	
	22	1800	
	22 dAZ	1800	
	33	1800	
	33 dAZ	1800	
	33 P	1800	
	211 dAZ	1800	
	311 dAZ	1800	
	411 dAZ	1800	
Micro Eleva	100 dAZ	1900	
Extra	11	1375	
	22	1375	
	22 AZ	1450	
	33	1375	
	33 AZ	1450	
	33 P	1375	
	211 AZ	1375	
	311 AZ	1375	
	411 AZ	1375	
Micro Extra	1425		
Solo	Solo	585	
	T dsc	499.33	
	T+ 311 dWDRC	798.66	
	T+ 311 Dsc	798.66	

Types	Subtypes	Price Phonak (€)	Price Lapperre (€)
	T+ 411 dSC	798.66	
	T+ 411 dLim	798.66	
	T+ 11	900	
	T+22	850	
	T+33	850	
Picoforte	3 PPCLP	900	800*
	3 PPCP	900	800
	3 PPSC	900	800*
	3 SC D	900	800
MAXX	11	1350	
	22	1300	
	211	1200	
	211 D	1300	
	311 Forte**	1200**	
	411 Forte**	1200**	

* Oddment at Lapperre
** On order at Lapperre

On order

Types	Subtypes	Price Phonak (€)	Price Lapperre (€)
Super Front :	PPC2	900	930
	PPCL4	1005	
	PPCL4+	1005	1050
Classica :	CD	850	700*
	PPSC	850	700*
	PPCP	850	700*
	PPCLP	850	700*
	AGC*	575*	
Savia :	111 dS	2200	
	111 dSZ open*	2250*	
	211 dSZ	2200	
	311 dSZ	2200	
	311 dSZ Forte*	2250*	
	11 RC**	**2250****	
	22 dSZ**	**2250****	
	22*	2250*	
	33*	2250*	
	33dSZ*	2250*	
	Microsavia 100 dSZ	2350	**2400****
Supero :	413 AZ	1750	1765*
	412	1400	1420*
	411	798.65	1040*

*On order or addment at Lapperre / not in the catalogue Phonak
**Line of goods at Lapperre

Oddment

Types	Subtypes	Price Phonak (€)	Price Lapperre (€)
Valeo	211	1400	1415
	211 AZ	1600	1615
	311	1400	
	311 AZ	1600	
	311 AZ Forte**	**1665****	
	311 Forte**	**1465****	
	Mini valeo101 AZ	1600	1615
	11	1665	
	23 AZ**	**1665****	
	22**	**1615****	
	33 Forte**	**1615****	
Aero	211	1200	
	211 AZ	1400	
	311	1200	
	311 AZ	1400	
Perseo	111 dSZ	2090	

** Lapperre

OTICON

5 Hearing aids types

10 Hearing aids subtypes

High prices	3	50%
Middle prices	2	20%
Low prices	5	30%

Types	Subtypes	Price (€)
Swift	70	501.08
	70+	501.08
	100+**	**501.08****
	120+**	**501.08****
Syncro	BTE*	2150*
	BTE Power*	2150*
Tego		1275
Sumo	**DM****	**1525****
	Sumo**	**1275****
P11P**		**765****

*Oddment
**On order

LAPPERRE

9 Hearing aids types
27 Hearing aids subtypes

High prices	9	33%
Middle prices	13	48%
Low prices	5	19%

Types	Subtypes	Price (€)
Lapperre 200	CIC	1130
	ITC	1030
	BTE	980
	ITE P**	**1030****
	ITE**	**1030****
	BTE P**	**1030****
Lapperre 1400	CIC	1450
	ITC	1400
	BTE	1300
	ITE P**	**1400****
	ITE**	**1400****
	BTE P**	**1350****
Lapperre 400	*+BTE**	*1250**
	*+BTEP**	*1350**
*E 311P**		*1535**
Easy	*WDRC BTE**	*800**
	*AGC BTE**	*700**
Eterna	Micro Eterna 100 dAZ	1900
	Eterna 211 dAZ	1900
	311 Daz**	**1900****
	411 dAZ**	**1900****
Ambia	211 AZ	1600
	311 AZ Forte	1600
	411 AZ Power	1600
Mini 4K		1600
My first	Right	501.08
	Left	501.08

*Oddment
**On order

Figure 43: Prices of hearing aids (Phonak/Lapperre).

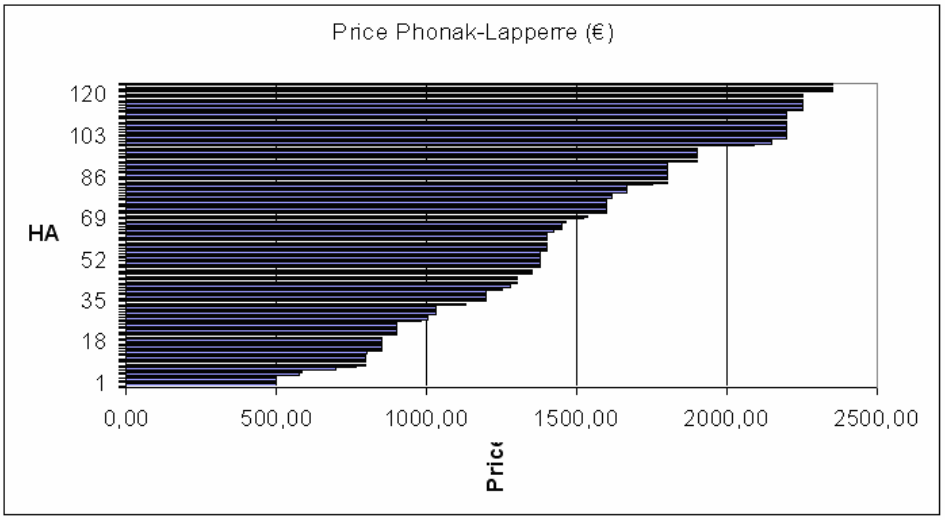
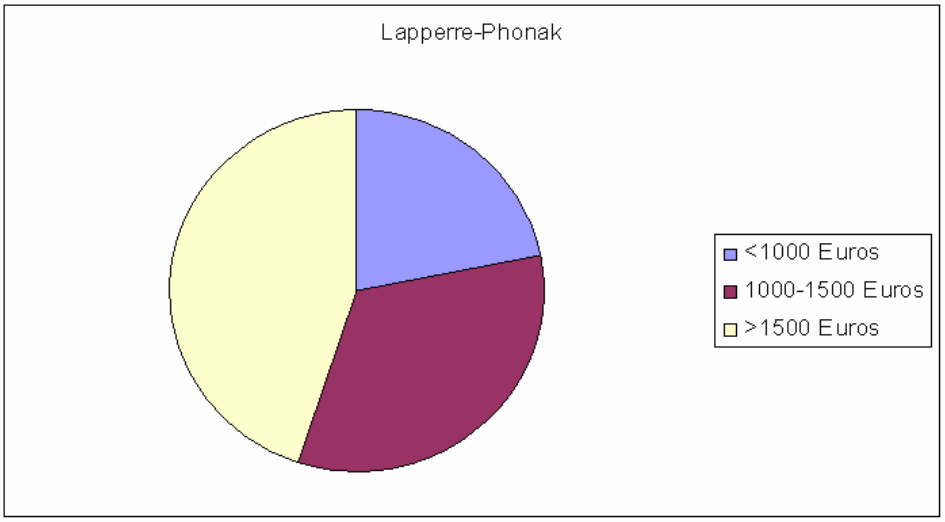


Figure 44: Hearing aids distribution by price (Phonak/Lapperre).



SIEMENS

7 Hearing aids types

14 Hearing aids subtypes

High prices	6	43%
Middle prices	3	21%
Low prices	5	36%

Types	**Subtypes**	**Price (€)**
Centra	HP	2100
	Life	2050
	S	2050
Acuris	ACuris	
	Acuris Life	1750
	P*	1800*
	S*	1700*
Prisma 2K		1200*
Cielo	Directionnel	1450
	Life	1300
Phoenix	313 avec trimpot	800
	113 avec trimpot	800
Lotus	13P	500
	13 SP	500
Intras Siemens	music-Swing Signa-Prisma CIC*	600*

*Available until the end of the stock

WIDEX

7 Hearing aids types

45 Hearing aids subtypes

High prices	21	47%
Middle prices	15	33%
Low prices	9	20%

Types	Subtypes	Price (€)
Inteo	IN 9 VC	1950
	IN 19 VC	1980
	IN 19 Elan VC	1900
	IN X	1950
	IN CIC	1980
Aikia	AK-9	1650
	AK-9 VC	1650
	AK-19	1700
	AK-19 VC	1700
	AK-9 ELAN	1650
	AK-9 ELAN VC	1650
	AK-XT	1650
	AK-CIC	1700
Senso Vita	SV 9	1450
	SV 9 VC	1450
	SV 19	1500
	SV 19 VC	1500
	SV 38 VC	1700
	SV-9 Elan	1400
	SV-9 Elan VC	1400
	SV X T (R-L)	1400
	SV X P	1450
	SV CIC	1650
Bravissimo	BV9 VC	1050
	BV19 VC	1150
	BV38 VC	1250
	BV8 Elan VC	1050
	BV X P	1250
	BV CIC	1250

Bravo	B1 VC	600
	B2 VC	780
	B11 VC	800
	B12 VC	860
	B32 VC	960
	B2X VC	900
	B2 CIC	1080
Widex	SD-9M*	1580*
	SD-9M VC*	1580*
	SD-19M*	1580*
	SD-19M VC*	1580*
	SD-9M Elan*	1580*
	SD-9M Elan VC*	1580*
Intras Widex	P7X VC*	800*
	P8X*	800*
	CXT+*	800*

*Available until the end of the stock

Figure 45: Prices of hearing aids (Veranneman).

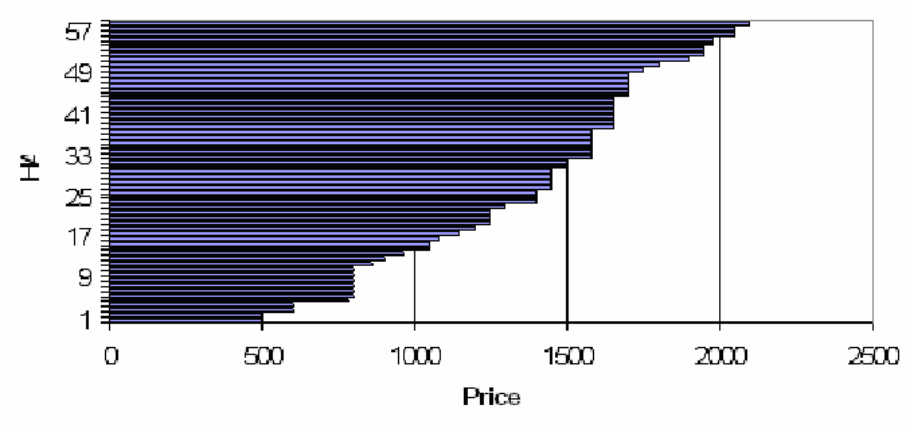
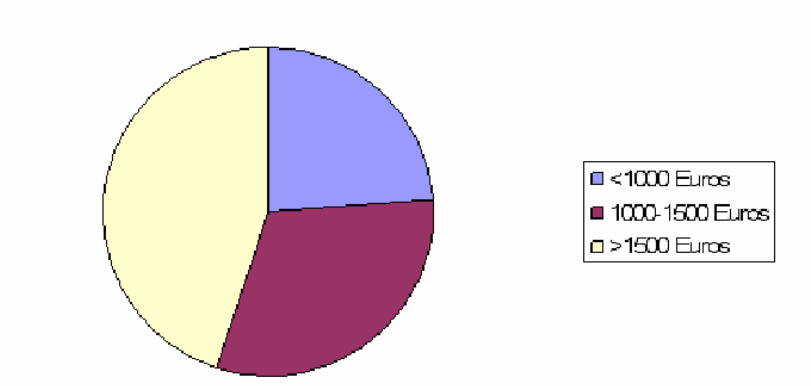


Figure 46: Hearing aids distribution by price (Veranneman).



Gn RESOUND

7 Hearing aids types

22 Hearing aids subtypes

High prices	12	55%
Middle prices	6	27%
Low prices	4	18%

Types	**Subtypes**	**Price (€)**
Discover	V	500
	V PBTE	500
	Plus	900
	Plus PBTE	1000
ReSound Vicking		1050
Canta	2 BTE (270)	1100
	2 PBTE (280)	1225
	2 ITC (230)	1225
	7 BTE (770D-open)	1900
	7 CIC (710/open)	2000
	7 PBTE (780D)	2000
ReSound Plus 5	MBTE	1450
	PBTE	1500
	MBTE°	1650
	PBTE°	1700
	CIC	1750
ReSound air		1800
Pulse		2200
Metrix	BTE	2220
	MBTE	2320
	PBTE	2370
	CIC	2475

Figure 47: Prices of hearing aids (Dialogue Gn resound).

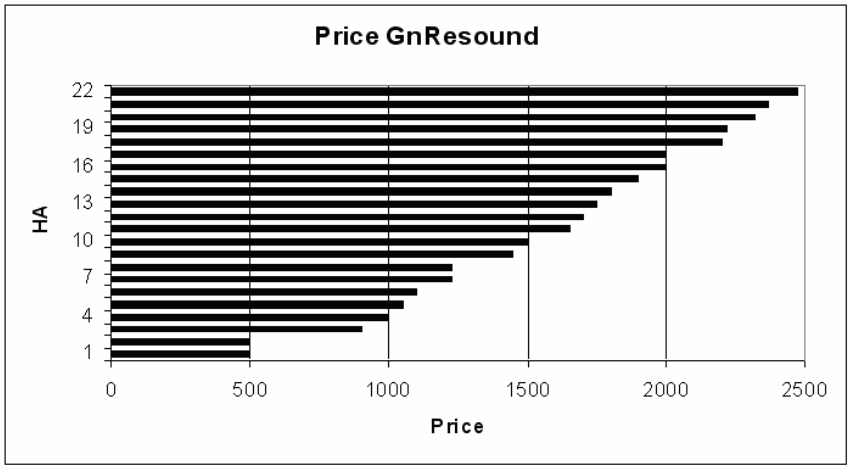


Figure 48: Hearing aids distribution by price (Dialogue Gn ReSound).

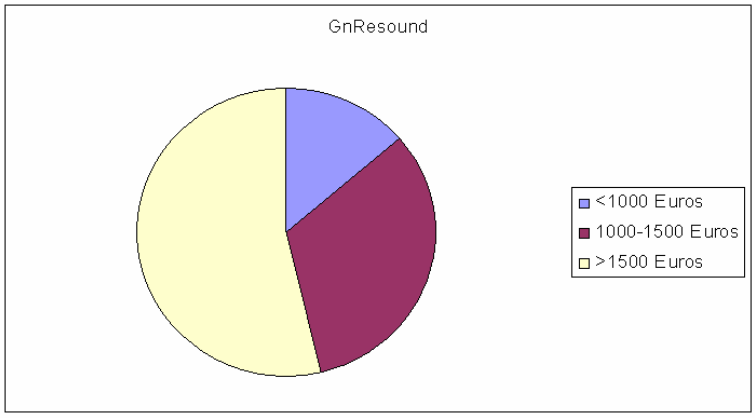
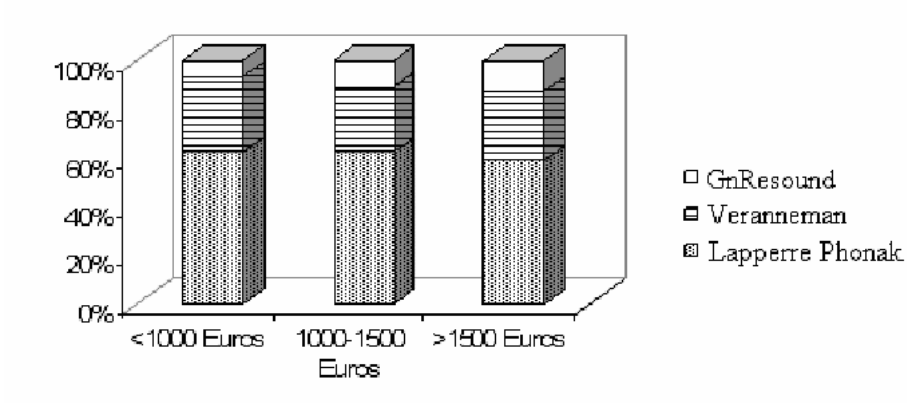


Figure 49: Hearing aids price distribution by importer.



Figure 50: Proportion available hearing aids by price for each importer.



APPENDIX TO CHAPTER 6 (INTERNATIONAL COMPARISON)

Additional Sources for the reimbursement conditions comparison

FRANCE

Patients below 20 years old are reimbursed on the basis of the TIPS, varying from €900/HA to €1400/HA	Arrêté du 25 août 2004 : Ministère de la santé et de la protection sociale : http://www.surdi13.org/audioprothese_fichiers/Arrete%2025%20aout%2004%20joe_20040909_0210_0032.pdf www.hear-it.org Interview of a French ENT Literature[117]
Usually, adults receive 65% of €200/HA. They have the right to a new HA every 3 years	Interview of a French ENT http://www.espaceaudition.com/catalog/rembourse.php Interview of an French ENT

GERMANY

30 dB in the best ear in only one frequency between 500 to 3000 Hz and with a speech discrimination score less than 80% at 65 dB.	1) Interview of a German ENT 2) http://www.fgh-gutes-hoeren.de/fgh/rund-ums-hoeren/besser-hoeren.html
For monaural fittings, 30 dB in 2000 Hz or in two frequencies between 500 to 3000 Hz	1) http://www.fgh-gutes-hoeren.de/fgh/rund-ums-hoeren/besser-hoeren.html
Tariff reimbursed	1) www.hear-it.org 1) http://www.fgh-gutes-hoeren.de/fgh/rund-ums-hoeren/besser-hoeren.html

THE NETHERLANDS

35 dB at 1000 Hz, 2000 Hz, 4000 Hz in the best ear.	1) Interview of an ENT 2) www.hear-it.org 3) http://www.beterhoren.nl/wps/wcm/connect/SiteCompanyNl/du/Hooroplossingen/Hoortoestellen/Vergoeding/ 4) http://www.hulpmiddelen.nl/doc%5Cfoldertekst2002.pdf
A 20% increase of words understood in speech audiometry (55dB) with the HA.	1) http://www.beterhoren.nl/wps/wcm/connect/SiteCompanyNl/du/Hooroplossingen/Hoortoestellen/Vergoeding/ 2) http://www.hulpmiddelen.nl/doc%5Cfoldertekst2002.pdf
Binaural fitting if the speech enhancement compared to monaural fitting is at least 10%.	1) http://www.hulpmiddelen.nl/doc%5Cfoldertekst2002.pdf
A hearing recovering of 45° in the localization test	1) http://www.hulpmiddelen.nl/doc%5Cfoldertekst2002.pdf
Tariff reimbursed	1) Interview of an ENT 2) http://www.beterhoren.nl/wps/wcm/connect/SiteCompanyNl/du/Hooroplossingen/Hoortoestellen/Vergoeding/

LUXEMBURG

No condition on hearing loss degree. Visit to the single audiologic centre in the country which chooses the most suitable HA.	1) Interview of an ENT

SWITZERLAND

30 dB in two frequencies between 500 to 3000 Hz	1) Interview of an ENT 2) www.hear-it.org 3) Société Suisse d'Oto-rhino-laryngologie et de chirurgie cervico-facial : « Recommandations aux médecins-experts AI pour la prescription et le contrôle des prothèses acoustiques »
Binaural fitting conditions	1) Société Suisse d'Oto-rhino-laryngologie et de chirurgie cervico-facial : « Recommandations aux médecins-experts AI pour la prescription et le contrôle des prothèses acoustiques »
Psychological conditions Social conditions Professional conditions	1) Interview of an ENT 2) www.hear-it.org 3) Société Suisse d'Oto-rhino-laryngologie et de chirurgie cervico-facial : « Recommandations aux médecins-experts AI pour la prescription et le contrôle des prothèses acoustiques »
Tariff reimbursed	1) Nouvelle convention tarifaire relative aux appareils acoustiques, valable dès le 1ère juillet 2006 : http://www.bien-entendre.ch/aktuelles/Folder.2006-07-06.3918/

UNITED KINGDOM

No condition on hearing loss degree.	1) Interview of an ENT
Visit to a public hospital + HA list	www.hear-it.org
The fitting is usually monaural	1) Interview of the NHS

DENMARK

Visit to a public hospital (list of HA). The best and cheaper HA is fitted free of charges.	1) www.hear-it.org
Reimbursed tariffs	1) www.hear-it.org
The expenses per head of population on hearing services are four times greater in Denmark than in UK.	Literature[117]

APPENDIX TO CHAPTER 7 (BUDGETARY EXPLORATIONS)

RIZIV/INAMI ARTICLE 31 BILLING CODES

RIZIVcode	Label_NL
679114	Forfaitaire tegemoetkoming voor het (de) individueel gevormd(e) gehoorstukje(s), wanneer er uiteindelijk geen hoorapparaat wordt afgeleverd na de tests
679136	Monofonisch toestel voor rechthebbenden van 18 jaar en ouder
679151	Monofonisch toestel voor rechthebbenden, jonger dan 18 jaar
679173	Stereofonisch toestel voor rechthebbenden van 18 jaar en ouder
679195	Stereofonisch toestel voor rechthebbenden, jonger dan 18 jaar
679210	Contralateraal toestel ten opzichte van de vorige aflevering om over te stappen op de stereofonische toerusting voor rechthebbenden van 18 jaar en ouder
679232	Contralateraal toestel ten opzichte van de vorige aflevering om over te stappen op de stereofonische toerusting voor rechthebbenden, jonger dan 18 jaar
679254	Monofonisch toestel voor rechthebbenden van 18 jaar en ouder
679276	Monofonisch toestel voor rechthebbenden jonger dan 18 jaar
679291	Stereofonisch toestel voor rechthebbenden van 18 jaar en ouder
679313	Stereofonisch toestel voor rechthebbenden jonger dan 18 jaar
679335	Contralateraal toestel ten opzichte van de vorige aflevering om over te stappen op de stereofonische toerusting voor rechthebbenden van 18 jaar en ouder
679350	Contralateraal toestel ten opzichte van de vorige aflevering om over te stappen op de stereofonische toerusting voor rechthebbenden, jonger dan 18 jaar
679372	Bijslag
679394	Forfaitaire tegemoetkoming voor het (de) individueel gevormd(e) gehoorstukje(s), wanneer er uiteindelijk geen hoorapparaat wordt afgeleverd na de tests

LITERATURE SEARCH

Date of Search = 17th November 2007

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1950 to Present>

Search Strategy:

1	prevalence.mp. [mp=ti, ot, ab, nm, hw]	(247565)
2	hearing.mp. [mp=ti, ot, ab, nm, hw]	(69755)
3	(dB$ or decibel$).mp. [mp=ti, ot, ab, nm, hw]	(62255)
4	freq$.mp. [mp=ti, ot, ab, nm, hw]	(782958)
5	presbycusis.mp. [mp=ti, ot, ab, nm, hw]	(230)
6	2 or 5	(69790)
7	1 and 3 and 4 and 6	(130)
8	limit 7 to yr="1990 - 2008"	(121)
9	limit 8 to "all adult (19 plus years)"	(91)
10	limit 9 to humans [Limit not valid in: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations; records were retained]	(91)
11	limit 10 to (dutch or english or flemish or french or german)	(88)
12	from 11 keep 1-88	(88)

AUDIOMETRIC REFERENCE VALUES°

Q	SEX	KEY_POP	POP06	POP10	POP20	POP30	KHz				U	B	2006		2010		2020		2030	
							1	2	4	MEAN			POP_M	POP_S	POP_M	POP_S	POP_M	POP_S	POP_M	POP_S
0,1	F	60 - 69F	516.949	578.805	694.057	714.316	5	8	10	8	0	0	0	0	0	0	0	0	0	0
0,3	F	60 - 69F	516.949	578.805	694.057	714.316	10	13	15	13	0	0	0	0	0	0	0	0	0	0
0,5	F	60 - 69F	516.949	578.805	694.057	714.316	15	18	25	19	0	0	0	0	0	0	0	0	0	0
0,8	F	60 - 69F	516.949	578.805	694.057	714.316	23	28	38	29	0	0	0	0	0	0	0	0	0	0
0,9	F	60 - 69F	516.949	578.805	694.057	714.316	33	40	50	41	1	0	51.695	0	57.881	0	69.406	0	71.432	0
0,1	M	60 - 69M	479.213	551.788	668.531	699.647	5	8	23	12	0	0	0	0	0	0	0	0	0	0
0,3	M	60 - 69M	479.213	551.788	668.531	699.647	8	13	35	18	0	0	0	0	0	0	0	0	0	0
0,5	M	60 - 69M	479.213	551.788	668.531	699.647	13	25	53	30	0	0	0	0	0	0	0	0	0	0
0,8	M	60 - 69M	479.213	551.788	668.531	699.647	23	40	65	43	1	0	119.803	0	137.947	0	167.133	0	174.912	0
0,9	M	60 - 69M	479.213	551.788	668.531	699.647	35	55	78	56	1	1	47.921	47.921	55.179	55.179	66.853	66.853	69.965	69.965
0,1	F	70 - 79F	486.392	468.772	518.087	631.242	10	13	18	13	0	0	0	0	0	0	0	0	0	0
0,3	F	70 - 79F	486.392	468.772	518.087	631.242	15	20	28	21	0	0	0	0	0	0	0	0	0	0
0,5	F	70 - 79F	486.392	468.772	518.087	631.242	23	30	40	31	0	0	0	0	0	0	0	0	0	0
0,8	F	70 - 79F	486.392	468.772	518.087	631.242	35	43	55	44	1	0	121.598	0	117.193	0	129.522	0	157.811	0
0,9	F	70 - 79F	486.392	468.772	518.087	631.242	45	53	65	54	1	1	48.639	48.639	46.877	46.877	51.809	51.809	63.124	63.124
0,1	M	70 - 79M	368.947	365.799	438.547	549.583	8	15	38	20	0	0	0	0	0	0	0	0	0	0
0,3	M	70 - 79M	368.947	365.799	438.547	549.583	13	25	53	30	0	0	0	0	0	0	0	0	0	0
0,5	M	70 - 79M	368.947	365.799	438.547	549.583	23	38	63	41	1	0	184.474	0	182.900	0	219.274	0	274.792	0
0,8	M	70 - 79M	368.947	365.799	438.547	549.583	35	55	73	54	1	1	92.237	92.237	91.450	91.450	109.637	109.637	137.396	137.396
0,9	M	70 - 79M	368.947	365.799	438.547	549.583	48	65	85	66	1	1	36.895	36.895	36.580	36.580	43.855	43.855	54.958	54.958
0,1	F	80 - 89F	262.814	306.278	310.977	371.056	18	25	35	26	0	0	0	0	0	0	0	0	0	0
0,3	F	80 - 89F	262.814	306.278	310.977	371.056	25	35	48	36	0	0	0	0	0	0	0	0	0	0
0,5	F	80 - 89F	262.814	306.278	310.977	371.056	35	45	58	46	1	1	131.407	131.407	153.139	153.139	155.489	155.489	185.528	185.528
0,8	F	80 - 89F	262.814	306.278	310.977	371.056	48	55	68	57	1	1	65.704	65.704	76.570	76.570	77.744	77.744	92.764	92.764
0,9	F	80 - 89F	262.814	306.278	310.977	371.056	58	68	78	68	1	1	26.281	26.281	30.628	30.628	31.098	31.098	37.106	37.106
0,1	M	80 - 89M	138.900	162.493	181.590	241.623	15	25	50	30	0	0	0	0	0	0	0	0	0	0
0,3	M	80 - 89M	138.900	162.493	181.590	241.623	25	38	63	42	1	0	104.175	0	121.870	0	136.193	0	181.217	0
0,5	M	80 - 89M	138.900	162.493	181.590	241.623	35	53	70	53	1	1	69.450	69.450	81.247	81.247	90.795	90.795	120.812	120.812
0,8	M	80 - 89M	138.900	162.493	181.590	241.623	50	63	80	64	1	1	34.725	34.725	40.623	40.623	45.398	45.398	60.406	60.406
0,9	M	80 - 89M	138.900	162.493	181.590	241.623	63	73	90	75	1	1	13.890	13.890	16.249	16.249	18.159	18.159	24.162	24.162
SUM OF MAXIMA PER AGE-SEX DEFINED GROUP													713.152	389.654	770.930	427.892	877.017	474.583	1.045.692	576.825

° Percentile-values on average (over 1-2-4 KHz) exceeding 39 or 44 DbHL are considered to correspond to a fraction of the Belgian population qualifying for respectively reimbursed unilateral or bilateral hearing aid fittings (indicated by value "1" in columns "U" and "B"). For instance, 25% of males aged 60-69 will qualify for unilateral HA fittings, meaning (100%-75%) X (479.213 males aged 60-69 in 2006) or 119.803 patients, will be added to our simulated population. This subpopulation of males beyond percentile 75 evidently includes the 47.921 males beyond percentile 90. As such the final simulated population is estimated by only adding the maxima in columns 2006-2010-2020-2030 per AGE-SEX defined subgroup.

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