Economic **I**mpact of **H**earing **L**oss in **F**rance and **D**eveloped **C**ountries

A survey of academic literature 2005-2015

FINAL REPORT
March 2016

Jean de Kervasdoué
Professor emeritus, Conservatoire National des Arts et Métiers

Laurence Hartmann
Senior lecturer, Conservatoire National des Arts et Métiers

List of abbreviations

AFL	Auditive functional limitations
ALD	Affection de longue durée
AMC	Assurance maladie complémentaire
AMO	Assurance maladie obligatoire
APA	Allocation personnalisée d'autonomie
APHAB	Abbreviated Profile of Hearing Aid Benefit
BLSA	Baltimore longitudinal study of aging
BS	Baromètre santé Survey
BSI	Brief symptom Inventory
BSSM	Baromètre santé sourds et malentendants Survey
CASF	Code de l'action sociale et de la famille
CEPP	Commission d'évaluation des produits et prestations
CEPS	Comité économique des produits de santé
CMUC	Couverture maladie universelle complémentaire
CNAMTS	Caisse nationale d'assurance maladie des travailleurs salariés
CNEDiMTS	Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé
dB	Decibel(s)
DREES	Direction de la recherche, des études, de l'évaluation et des statistiques
DSS	Direction de la sécurité sociale
EHIMA	European Hearing Instrument Manufacturers Association
ENT	Ear, Nose and Throat specialist
ESPS	Enquête santé et protection sociale Survey
EQ-5D	Quality of life questionnaire EuroQol
HA(s)	Hearing aid(s)
HAS	Haute Autorité de Santé
HCAAM	Haut Conseil pour l'avenir de l'assurance maladie
HID	Handicaps-Incapacités-Dépendances Survey 1998
HUI3	Quality of life questionnaire Health utilities index Mark 3
IGAS	Inspection Générale des Affaires Sociales
ICER	Incremental Cost-Effectiveness Ratio
INSEE	Institut National de la Statistique et des Etudes Economiques
InVS	Institut National de Veille Sanitaire
INPES	Institut National de Prévention et d'Education à la Santé
MMSE	Mini mental state examination
NHANES	National health and nutrition examination survey
NHI	National Health Insurance
NHS	National Health System
NICE	National Institute of Clinical Excellence
OCAM	Organismes complémentaires d'assurance maladie
OECD	Organisation for Economic Cooperation and Development
OOP	Out-of-pocket
PCH	Prestation de compensation du handicap
PHQ9	Patient health questionnaire - depression
QALYs	Quality adjusted Life Years
ROSP	Rémunération sur objectifs de santé publique
RQTH	Reconnaissance de la qualité de travailleur handicapé
SF12	Quality of life questionnaire Short form 12 dimensions
SNIIRAM	Système national inter-régimes de l'assurance maladie
SNITEM	Syndicat National de l'Industrie des Technologies Médicales
UNPS	Union Nationale des Professionnels de Santé
UNSAF	Union Nationale des Syndicats des Audioprothésistes Français
VAT	Value added-tax
VSL	Value of statistical life
WHO	Worldwide Health Organisation
WHO-QoL	Quality of life questionnaire of WHO

Contents

Summary

Hearing loss in France affects about 10% of the population, namely over 6 million people have to face hearing difficulties in daily life. Older adults (over 50 years old) are the most concerned – one third of this population – as hearing loss arises during the course of life (for 88% of French people), through a natural and progressive phenomenon (presbycusis) or after exposure to noise. In Europe, Japan and the United States, prevalence rates are comparable to those in France. The WHO estimates this burden of illness to currently concern more than 5% of the global population, representing 360 billion people. Nowadays, hearing loss is considered as *a major public health issue in the scientific literature and by international health agencies.*

Not only is hearing loss apparent through direct functional limitations (understanding and communication difficulties), but *hearing impairment is also associated with a higher frequency of mental disorders, cognitive decline, falls and even mortality, independently of ageing effects.* Hearing loss could precipitate the elderly into dependency. Hearing aids ('medical devices for individual use') compensate, to a certain extent, for hearing impairment and, furthermore, ensure some individual rehabilitation: *in 2015, more than 2 million French people owned hearing aids out of 3 million eligible people. This technical solution should be further encouraged, since 1 million French people declare a need for hearing aids but don't get them.*

As a result, improving access to hearing aids represents a decisive issue, not only in terms of financial accessibility and fairness, but also in terms of efficiency: *hearing aid equipment is presumed to reduce the significant implications of hearing loss on health state and healthcare expenditure and, thus, improve the patient's quality of life.* Yet, the hearing aid sector in France has been long characterized by a wait-and-see public policy: the regulatory rules have been frozen for several decades, due to a lack of reliable information on the expected added value of hearing aids (in economic terms of utility). This lack of information and stalled regulations have resulted in several recent reports, released by the Court of Accounts (*Cour des comptes*) and the General Inspectorate for Social Affairs (*Inspection générale des affaires sociales*), which both underline the urgent need to re-examine the access rules to hearing aids and to provide, at the same time an economic assessment of this equipment.

The main obstacle to hearing aid access in France (financial barrier) concerns current financing rules, and particularly the public trade-offs that have led hearing aids to be classified in the 'low risk' category and practically excluded from socialised health care. This classification implicitly indicates that the hearing aid is a luxury product whose medical added-value is very low: *in comparison to the trade-offs for drug classification, the hearing aid medical added-value ranges between 'low' and 'insufficient', since its observed reimbursement rate is under 15%.* Yet, wide access to hearing aids (2/3 in terms of 'real access' of the eligible population) shows clearly that demand elasticity is low: they are a necessary item. In general, the public choice of coinsurance depends on the combination of 'low risk' and 'commitment'. There is only partial reimbursement in relation to 'low risk', or even totally exclusion from the social health care basket when it does not depend on the collective responsibility and implies an individual judgement on the trade-off consumption-price (in order to avoid over-consumption or, in economics, the 'moral hazard' risk). Yet, not only is access significant despite the out-of-pocket payment, but moreover its health consequences as well as its economic impact are

likely to be major. The cost to society of hearing aid renunciation, in terms of quality of life, expenditure and social inequalities is in total opposition to the objectives assigned to the French health system.

Hearing loss: outline data

Disabling hearing loss prevalence is estimated today to range between 8.6% and 11.2% of the overall French population. The analysis of hearing aid access shows that 30% to 35% of hearing impaired people are equipped, namely 2 million out of 6 million people. *This gap is reduced when considering people being equipped and people eligible for hearing aids: whatever the expert assessments, survey data or empirical statements (monographs by country), only half of hearing impaired people would be eligible for hearing aids, thus 3 million people in France.* Thus, 65% of eligible French people are hearing aid owners whereas 35% of them remain unequipped.

There are two main reasons which can explain this renunciation: a low public and private coverage (provision), and a lack of information. Indeed, the average price for one hearing aid comes to 1,535 euros, and 3,070 euros for binaural equipment. But this expense is poorly covered by the National Health Insurance (8%) and poorly reinsured by complementary health insurances (30%), leaving a high out-of-pocket payment for the adult insured (62%), namely 950 euros per apparatus. The price for hearing aid equipment comprises both the device and the audiologist's counselling and follow-up services.

For the hearing aid owners, the equipment has an average duration of 5 to 6 years, during which a qualified check-up is ensured by the audiologist. *The quality of the equipment as well as the quality of the follow-up should influence hearing aid efficiency, user satisfaction and beneficial compliance.* This hypothesis seems to be confirmed throughout international comparisons: in countries where access rate to hearing aids is higher, the social coverage is better for downmarket or middle market equipment. However, these countries don't necessarily have greater rates of *real* HAs users (i.e. rates considering *effective* eligible people for hearing aids and *effective wearing* of hearing aids). Taken thus, France would present a *real* rate of use close to those of the United Kingdom, Germany and Norway and starting from very different situations in terms of financial access to equipment. If there is room for improvement in France regarding the need for hearing aid equipment – due to financial impediment - there is also room for growth in countries where hearing aids are (almost) freely delivered but where the compliance isn't sufficiently performant. *A review of financial rules relating to hearing aids has to consider the compliance factors determining the effective use of equipment and, thus, the level of satisfaction for hearing aid users.*

Concerning the payment schemes for audiologists, an economic analysis is necessary, taking into account their incentive properties. In order to regulate the hearing aid sector and to design an incentive payment for hearing aids, a trade-off is necessary between the objectives of expenditure control, health care quality and freedom of choice, in a hypothetic framework assuming a higher coverage of hearing aids. There are many tools allowing us to realise the optimal trade-off for public financing, but a cautious approach is *required regarding the issue of a possible decoupling of the device and the service*. This decoupling model brings up adverse effects which are similar to those of 'cost-plus' payment, leading to increasing prices and

putting patients' compliance at stake, i.e. affecting the therapeutic efficiency of hearing aids for some of them. At the same time that recourse to prospective payment systems is increasingly implemented for pricing in health systems, and as growing attention is paid to patients' empowerment, this concept of divisibility device/service falls within a backwards economic approach in terms of optimal incentives. International comparisons highlight the impact of coverage and health care organisation on hearing aid access, equipment renewal and patients' compliance. They show also that French prices for one hearing aid are very similar to those of other European countries.

Health and economic consequences of hearing loss: impact study

International medical scientific literature as well as French survey data are profuse on the burden of illness topics and these start to provide evidence-based studies on the causal alleged connection between hearing loss and health state degradation. Disabling hearing loss (or moderate to total auditive functional limitations), by reducing the person's communication capacities, rebounds significantly onto the whole dimensions of health state (mobility, autonomy, daily activities, pain/discomfort, anxiety/depression) through a succession of chain reactions, the main ones being *social isolation, cognitive decline, suffering at work, mental troubles and falls*. Hearing loss represents a major impairment which, by affecting more than six million (often older) French people, *not only has deleterious effects on quality of life but also leads to additional health and social care expenditure for society as a whole.*
The scientific literature unambiguously reports the negative waterfall effects of hearing loss, but also show the beneficial effects of hearing aid wearing: reduced mortality risk; improved psycho-social health state; and a normalising effect on cognitive decline risk. Publications also point out that this favourable impact on mental health is appreciable starting from the first 3 months of equipment. In the same perspective, some studies show the reliability and the efficiency of earlier screening for people at the end of their working lives, screening those who are old enough to justify secondary prevention, but young enough to benefit from it since their hearing loss level is moderate to severe. Earlier screening appears to be a very efficient strategy regarding cost and quality of life. *It should be implemented over the course of medical consultations, in the form of two short questions without additional costs to general practice.*

Starting from this literature and the survey data, two scenarios for economic assessment of hearing loss are proposed. The first one gives rough estimates for intangible costs related to quality of life degradation in France. The aim is to assess the monetary value of lost healthy years by valuing them in terms of the implicit price of human life. Based on realistic assumptions, this estimation draws an image of saved costs thanks to hearing aid equipment or compliance, as well as the economic burden of hearing loss related to its prevalence: without equipment, this burden would amount to 23.4 billion euros. The real rate of equipment (effective access and effective use of hearing aids) reduces this burden by 30%, whereas the target equipment rate (i.e. 50% of hearing impaired people related to actual compliance) would lighten the burden by 40%.

The second scenario relies on several assumptions in order to estimate, on the one hand, medical costs related to hearing loss without equipment and, on the other hand, average scores of lost utility related to quality of life. Both dimensions are graduated according to French hearing loss prevalence rates by age groups and by severity levels, then they are

connected with the rate of eligible people for hearing aids but who are not being equipped. For this specific population, we assume that a gain should be expected in quality of life and in cost savings, if equipment were delivered for 6 years. Assessing these values allows us to roughly estimate a range for the incremental cost-utility ratio, expressing the cost to pay in order to gain one additional healthy year for the period. Yet, through this simple simulation, *the target strategy (i.e. equipment for eligible population not accessing hearing aids) would be dominant, even taking into account the compliance rate that reduces quality of life gains and costs savings: the overall cost of this additional equipment would be 1.5 billion euros, with 48,000 QALYs gained and with cost savings worth 1.7 billion euros, namely a ICER of - 830 euros/QALY.* In other words, the target strategy of 'all eligible people are equipped' saves costs and provides an increased quality of life, and is thus the dominant strategy. This entire case study, which relies on acceptable assumptions, underlines the requirement for a substantial economic assessment that would corroborate these results, that is the highly efficient target strategy that 'all eligible hearing impaired people are equipped', since the annual overall expenditure of the hearing aid sector comes close to 1 billion euros. However, it remains to solve the touchy question of hearing aid financing likely to support access to them, and especially the question of the relative financial contributions of payers, as seen in the first section of the report. Moreover, if the National Health Insurance could greatly increase its financial role in hearing aid reimbursement, we would anticipate a bounce effect for people being equipped but having postponed hearing aid renewing. This effect would inevitably increase the budget impact of hearing aid access. That's why an overall scenario has to be set up, through prospective cost-efficiency assessments, by collecting useful data in sequential or regular surveys based on the working and older population, in order to infer the differential cost-utility ratio between strategies. This overall scenario would be completed by estimating the budget impact of hearing aid equipment depending on several coverage scenarios from the National Health Insurance's point of view.

Coming out of this overview, the health policy for secondary prevention, that could consist of screening and equipping hearing impaired people with hearing aids, is non-existent regarding public reimbursement. National Health Insurance, by covering only 8% of hearing aid price for adults, has almost excluded hearing loss from its management policy for health risk, leaving the out-of-pocket payment to complementary insurance bodies and above all to patients. *In fine*, families, close relatives and the whole society bears the costs of this impairment, as well as for the loss of autonomy since one third of the eligible population for hearing aids don't get to them. Moreover, inequalities relating to the rights of those insured with complementary health bodies, their revenue and ability to pay for equipment contribute to maintain these social inequalities in health, by the renouncement effect. These statements would impose the need for an urgent examination of the regulatory rules for the hearing aid sector in France, at a moment where ageing, and listening to amplified music among the young risks contributing to aggravated hearing loss prevalence in France.

Introduction

In France, over 6 million people have disabling hearing loss, leading to difficulties in daily life. Older adults (over 50 years old) are the most concerned – one third of this population – as hearing loss arises during life course (for 88% of French people), through a natural and progressive phenomenon (presbycusis) or after exposure to noise.

Not only is hearing loss apparent through direct functional limitations (understanding and communication difficulties), but hearing impairment is also associated with a higher frequency of mental disorders, cognitive decline, falls and even mortality, independently of ageing effects. Hearing loss could precipitate the elderly into dependency. Medical scientific literature is profuse on this topic and starts to provide evidence-based studies on the causal alleged connection between hearing loss and health state degradation. Moreover, it highlights the burden of illness and its impact on healthcare consumption and expenditure. Therefore, hearing loss is a major topic for public health.

Hearing aids compensate, to a certain extent, for hearing loss and, furthermore, ensure some individual rehabilitation: in 2015, more than 2 million French people owned hearing aids. However, this technical solution should be further encouraged, since 1 million French people are eligible for hearing aids but don't get them. There are two main reasons which can explain this renunciation: a low public and private coverage (provision), and a lack of information. Indeed, the average price for one hearing aid comes to 1,535 euros, and 3,070 euros for binaural equipment. But this expense is poorly covered by the National Health Insurance and poorly reinsured by complementary health insurances, leaving a high out-of-pocket payment for the insured.
As a result, improving access to hearing aids represents a decisive issue, not only in terms of financial accessibility and fairness, but also in terms of efficiency: hearing aid equipment is presumed to reduce the significant implications of hearing loss on health state and healthcare expenditure and, thus, improve the patient's quality of life. Yet, the hearing aid sector in France has been long characterized by a wait-and-see public policy: the regulatory rules have been frozen for several decades, due to a lack of reliable information on the expected added value of hearing aids (in economic terms of utility). This lack of information and stalled regulations have resulted in several recent reports, released by the Court of Accounts (*Cour des comptes*) and the General Inspectorate for Social Affairs (*Inspection générale des affaires sociales*), which both underline the urgent need to re-examine the access rules to hearing aids and to provide, at the same time an economic assessment of this equipment.

Economic assessment of hearing aids should corroborate their efficiency and, if relevant, should lead to a correction of the scope for social reimbursement, as far as the budget impact on National Health Insurance is affordable. Such an assessment requires thinking in terms of utility and quality of life for people wearing hearing aids and to compare the cost-utility ratio of equipment with respect to non-equipment. In line with these questions, another issue is the reliability of hearing loss screening in order to prevent early loss of autonomy. Should a generalised screening program be considered appropriate for people at the end of their working lives? If so, under which conditions and for what efficiency?

The purpose of the present study is to gather and review the major papers in the scientific literature as well as the grey literature released on this topic over the period 2005-2015. We put this literature into perspective using some economic tools in order to propose an economical framework for regulatory analysis of the hearing aid sector. Then, we bring forward rough estimates for the cost and the utility of hearing aids.

This report is structured in two main sections as follows: section 1 focuses specifically on hearing loss in France and presents the rules which organise access and delivery of hearing aid equipment. An international comparison for key countries in Europe is addressed when similar collection of data is available. Section 2 outlines the global burden of hearing loss, on the basis of key papers released in the medical scientific literature. As an extension of this survey, a hypothetical scenario for economic assessment is set out on the basis of available data for France.

1 Hearing loss: outline data

Hearing loss prevalence in France and its consequences on health state emphasize this public health issue, even though there are differing definitions: approximately 16% of French people report some difficulties with hearing (in the broadest sense, defined by 'auditive functional limitations') whereas disabling hearing loss affects 8.6% to 11.2% of French people (defined by 'disabling hearing loss') (Haeusler and al., 2014 ; EHIMA, 2015)[1]. Hearing loss affects mostly adults aged 50 years and over (progressive hearing impairment with older age or presbycusis).

In the general case, hearing loss alleviation relies on the use of hearing aids (HAs), which are a 'medical device for individual-use' in the French classification. The analysis of access to hearing aids is tricky because not only is available data lacking, but values are variable between sources, surveys or databases. There is an obvious and important gap between people being fitted with a prosthesis (in the study, 'hearing aid owners') and people with disabling hearing loss: only 30% to 35% of the latter are hearing aid owners[2].

The average price for one hearing aid (HA) is around 1,535 euros, while social coverage is particularly low (120 euros for one ear, that is a basis for social reimbursement of 200 euros associated with a coinsurance rate of 60%). Hence, the gross out-of-pocket sum is likely to represent a high barrier to access, in that complementary insurance covers a minor part of it. There is also significant inequality between beneficiaries due to the diversity of contracts. Indeed, the net out-of-pocket sum is estimated to be 62% of the total price (i.e. 958 euros apiece) and is associated with healthcare renunciation. For the hearing aid owners, the equipment has an average duration of 5 years, during which a qualified check-up is ensured by the audiologist: the price comprises both the device and the service. The quality of the equipment as well as the quality of the follow-up should influence user satisfaction and beneficial compliance.

This hypothesis seems to be confirmed throughout international comparisons: starting from the data of the EHIMA (2015) and on the basis of the methodology of Alcimed-CNSA (2009), we can state the fact that in countries where access rate to hearing aids is higher, the social coverage is better for downmarket or middle market equipment. However, these countries don't necessarily have greater rates of *real* HAs users (i.e. rates considering *effective wearing* of hearing aids). Taken thus, France would present a real rate of use close to 61% (combining the rate of *eligible people for hearing aids* and the rate of *effective* use), a rate similar to those of the United-Kingdom, Germany and Norway and starting from very different situations in terms of financial access to equipment. If there is room for improvement in France regarding the need for hearing aid equipment – due to financial impediment - there is also room for growth in countries where hearing aids are (almost) freely delivered but where the

[1] There is some variability in estimations of the number of people affected by hearing loss, depending on the fields of surveys and their methodology. In this study, we qualify hearing loss in the broad sense when it includes slight limitations not associated with a need for hearing aids, and disabling hearing loss (or hearing loss in the strict sense of the term) when the impairment has an impact upon the daily activities.

[2] As shown further, these estimations are widely variable in surveys. Moreover, the report will focus on the difference between *people able to be equipped* and *people with disabling hearing loss*. Hence, these estimations have to be taken as approximations.

compliance isn't sufficiently performant. A review of financial rules relating to hearing aids has to consider the compliance factors determining the effective use of equipment and, thus, the level of satisfaction for hearing aid users. A trade-off has to be undertaken between, on one hand, financial access and, on the other hand, suppliers' and users' commitment to hearing aid use.

1.1 Prevalence of hearing loss and auditive functional limitations in France

From a technical and medical perspective, hearing loss refers to ranges of decibels (dB) that cannot be heard by a person : ranging between 0 to 20 dB, audition is normal or sub-normal; 21-40 dB, impairment is slight; 41-70 dB, impairment is moderate; 71-90 dB, impairment is severe; 91-119, impairment is profound and beyond 120 dB impairment is total (deafness)[3].

The Worldwide Health Organisation (WHO) suggests a categorisation of hearing impairment into five grades (table 1):

Table 1 – Grades of impairment in WHO classification

Grade of impairment	HL in better ear	Qualitative description	Recommendations
0 No impairment	25 dB or better	No or very slight hearing problems	
1 Slight impairment	26 - 40 dB	Able to hear and repeat words spoken in normal voice at 1 metre	Counselling. Hearing aids may be needed.
2 Moderate impairment	41 - 60 dB	Able to hear and repeat words using raised voice at 1 metre	Hearing aids usually recommended.
3 Severe impairment	61 - 80 dB	Able to hear some words when shouted into better ear	Hearing aids needed. If not available, lip-reading and signing should be taught.
4 Profound impairment including deafness	81 dB or greater	Unable to hear and understand even a shouted voice	Hearing aids may help understanding words. Additional rehabilitation needed. Lip-reading and sometimes signing essential.

Source: Shield, 2006. Always reference values on www.who.int (8 March 2016)

Shield (2006) underlined the variability of definitions and levels of hearing impairment severity between health organisations, as shown in table 2. This variability is one of the factors explaining the differences of hearing loss prevalence in the same country, according to the national and international sources.

[3] Classification of the international committee of audio-phonology – BIAP (cf. www.biap.org on 8th of March 2016). Leusie's study (2015) brings up the idea of "very slight hearing loss" or "subclinical hearing loss", a grade of hearing loss being between 15 and 25 dB, from which it would be appropriate to take action. Cf. p123-124.

Table 2 – Variability of reference values in hearing impairment classifications

	None	Mild	Moderate	Moderate - severe	Severe	Profound
WHO (avg. 0.5, 1, 2, 4 kHz)	≤ 25	26 - 40	41 - 60		61 - 80	≥ 81
European Commission (avg. 0.5, 1, 2, 4 kHz)	≤ 20	21 - 39	40 - 69		70 - 94	≥ 95
ANSI	≤ 26	27 - 40	41 - 55	56 - 70	71 - 90	≥ 91
RNID		25 - 39	40 - 69		70 - 94	≥ 95
BSA (avg. .25, .5,1,2,4 kHz)		20 - 40	41 - 70		71 - 95	>95
NIDCD (avg. 0.5, 1, 2, 3 kHz)	<25		~ 40		≥ 75	

WHO : Worldwide Health Organisation ; ANSI : American National Standards Institute ; RNID : Royal National Institute of Deaf and hard of hearing people ; BSI : British Society of Audiology ; NIDCD : National Institute of Deafness and other Communication Disorders.

Source: Shield, 2006

The quantitative measure of hearing levels in dB, performed by the ear, nose and throat specialist (ENT specialist) or the audiologist, doesn't allow for a direct estimation of the hearing loss prevalence in the general population, as far as this measure occurs when a consultation is effective (in others words, there is a long time between the occurrence of disabling hearing loss and healthcare access and the needs for hearing aids cannot be appreciated only through health care consumption). The estimation of hearing loss prevalence relies in general on population studies and self-reported qualitative data. The ten-yearly French survey '*Handicap-Santé*' (i.e. '*Impairment-Health'*) 2008, carried-out by two French national institutes of statistics, the INSEE and the DREES, and released in 2014, is the main declarative French survey allowing an estimation of hearing loss prevalence and an appraisal of auditive functional limitations (Haeusler, Mordier, 2014; Haeusler and al., 2014; InVS, 2015)[4]. However, given that the data were collected in 2008, it is advisable to bring them up to date, on the basis of a few hypotheses and on other recent data sources, as follows.

1.1.1 Estimations of hearing loss prevalence in "*Handicap-Santé"* French survey 2008

Following the "*Handicap-Santé*" survey 2008, hearing impairment is recognised either through individual statements of using hearing aids or statements of a need for hearing aid equipment. In this way, 1,112,000 people were hearing aid owners in 2008, whereas 2,043,000 people declared a need for hearing aid equipment (being 35% of the equipment for the whole population eligible for hearing aids). This population represented more than 3 million people affected by a level of hearing loss significantly damaging their health status (table 3).

[4] Data are gathered from several surveys, of which the latest in France is the "*Handicap-Santé*" survey, implemented in 2008. Estimated statistics reported by Haeusler and Mordier (2014) rely on a panel sample of 28,500 people and are extrapolated to the French whole population. Estimated statistics reported by Haeusler and al. (2014) are based on qualitative statements of 30,000 people in ordinary households and 9,000 people in institutions.

Table 3 – Number of people who are hearing aid users or declaring a need for hearing aids in 2008

Are you a hearing aids user ?	Number of people	% of total population
Yes	1 112 000	1.8%
No, but I would need to use them	2 043 000	3.2%
No and I don't need them	59 875 000	94.9%
Doesn't know, withdraws from answer	54 000	0.1%
Total population	**63 084 000**	**100%**

Source: DREES, 2014

Moreover, the number of people declaring at least one hearing impairment rises to more than 7 million – being 11.2% of the French population – provided that every type of disability is included in the survey (table 4). Therefore, from deductions based on the data in table 3 and table 4, the rate of equipment relative to disabling hearing people is close to 15.8% in 2008.

Table 4 – Number of people declaring hearing impairments

Hearing loss : do you have some hearing troubles ? (hard of hearing, tinnitus). If yes, which ones ?	Number of people	% of the total population
Deafness	182 000	0.3%
Hard of hearing	1 062 000	1.7%
Single-sided deafness	974 000	1.5%
Other hearing loss but neither hard of hearing, nor deaf	3 153 000	0,05
Other hearing trouble (tinnitus, buzzing, ringing in the ears…)	2 012 000	3.2%
At least one hearing impairment	**7 056 000**	**11.2%**

Source: DREES, 2014

In the 2008 survey, disabling hearing, on one hand, is estimated directly by 'hearing impairment' (hearing aids users/declared need for a hearing aid, hearing disability) and, on the other hand, is assessed indirectly by 'auditive functional limitations' (for instance, difficulty to hear in a conversation with several participants). The prevalence data are then reckoned by the authors on this double source (hearing impairment and auditive functional limitations). Auditive functional limitations (AFL) are classified into four levels of severity in order to identify them in the survey (table 5).

Table 5 – Reference groups of severity for auditive functional limitations (AFL)

Level of AFL	Rule for findings
Very severe or total	Cannot hear at all a conversation with several participants and declares him/herself to be deaf (single-sided or double-sided) or hard of hearing
Severe	Has a lot of difficulties to hear a conversation with several participants or cannot hear at all a conversation with several people and declares a hearing impairment other than deafness (single-sided or double-sided) or hard of hearing
Moderate	Has some difficulties to hear a conversation with several participants or being a person equipped with hearing aids and able to follow a conversation without any difficulty or being a person hard of hearing or being a person single-sided deaf having declared a need for hearing aids and following a conversation without any difficulty
Slight	Has some difficulties to hear a conversation, but hasn't a declared hearing impairment or hasn't difficulties to hear a conversation and declares a hearing impairment such as tinnitus or ringing in the ears and doesn't use hearing aids

Source: DREES, 2014

In 2008, 10 million people were affected by AFL: this was 16.1% of the main population.

Moderate to severe AFL (three levels of severity higher) affect 5.4 million people (8.6% of the general population) and 16% of them have a social recognition of invalidity or disability for their impairment (amongst people younger than 60 years). Among this social recognition group, only 2% are found in an institution (whereas 10% of people with very severe or total AFL live in an institution)[5].

Table 6 – Whole prevalence of auditive functional limitations (AFL) due to hearing loss in France

Auditive limitation scale	Number	Confidence interval 95%	%
Not any problem*	52 931 000	52438000-53424000	82,50%
Slight	4 730 000	4471000-4989000	8%
Moderate	3 474 000	3264000-3684000	5,90%
Severe	1 600 000	1477000-1723000	2,70%
Profound or total	359 000	311000-406000	0,60%
Whole population	63 094 000		100%
Total with auditive limitations	**10 163 000**	**9822000-10503000**	**16,10%**
Including moderate to profound	5 433 000	5190000-5675000	8,61%

Field : People living at home or in institution

Sources : Disability-health survey 2008 ('enquête Handicap-Santé 2008')

*including 1 353 000 people not able to answer the question about conversation (young people or having heavy impairments)

Source: DREES, 2014

The overall AFL concern 15.9 % of people living at home, 18% of people living in institutions for disabled persons and 42% of people living in institutions for the elderly[6]. In other words, people living in institutions are more frequently affected by AFL.

1.1.2 Estimated data for hearing loss prevalence in 2015

The Eurotrak data 2015 released by the EHIMA (European Hearing Instrument Manufacturers Association) are based on a qualitative survey relying on a representative sample of 14,824 French people. Hearing loss prevalence was stated to be around 9.3% of the general population (11.4% for people older than 18), and this estimation has been steady since 2009 (2009 : 10.4% ; 2012 : 9.4%)[7].

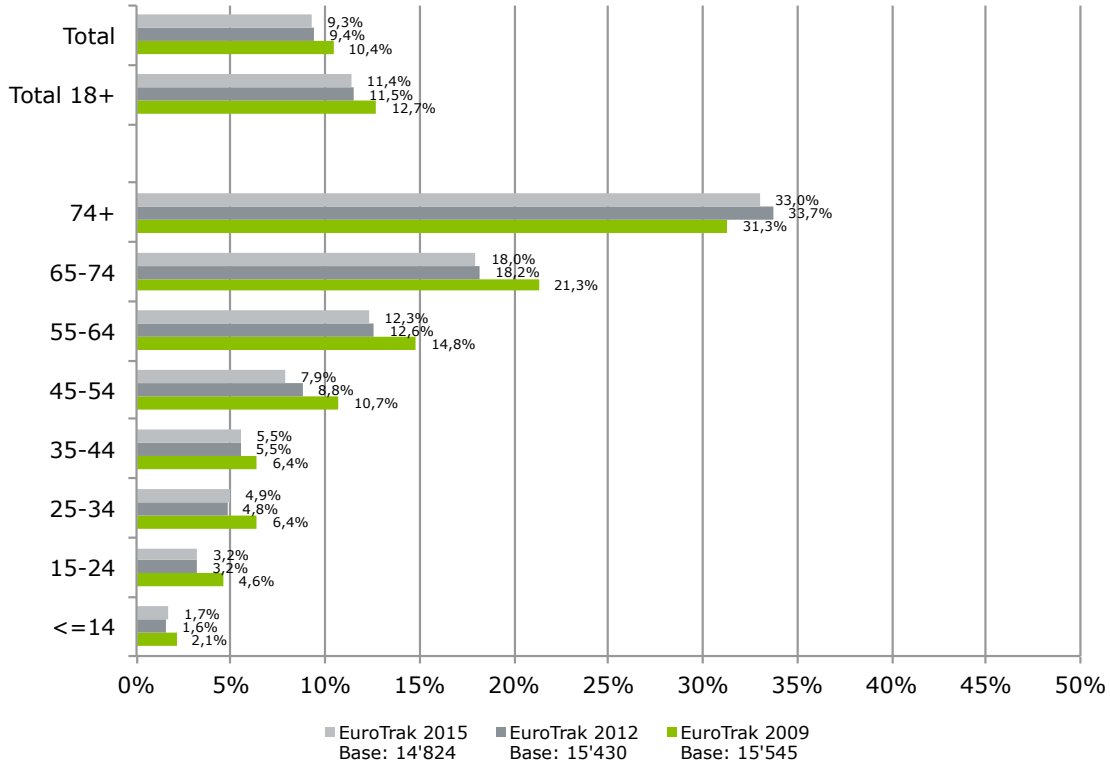
---

[5] As underlined by the DREES (Haeusler and al., 2014), the "*Handicaps-Incapacités-Dépendances*" ('*Impairments-Incapacities-Dependencies*') 1998 survey assessed 5.2 million people affected by moderate to total hearing difficulties, including 303,000 people concerned by very severe to total AFL. These estimations appear to be steady over time, despite some differences in the assessment method.

[6] Thus, 36.2% of people in institutions are affected by slight to total AFL. However, the DREES considers that there is probably an understatement of hearing loss among the elderly in institutions, because hearing loss might be judged as "normal" in relation to other impairments which are likely to be more marked (Haeusler and al., 2014, p.20).

[7] Since 2009 the EHIMA association has conducted a triennial survey into the major European markets (France, Germany, United Kingdom), which has extended since 2012 to Switzerland, Denmark, Norway and Italy as well as to Japan. The methodology for the survey reproduces that of one of the American models, Marketrak. Its conception, design and conduction are operated by a Swiss company (Anovum). Thus, because of a similar methodology for surveys on significant panels of the national population (on average 14,000 people in samples), the data allow some international comparisons. Moreover, it should be underlined that these EHIMA data are put into perspective in the DREES report 2014 and are consistent with French data released in national surveys.

Chart 1 – Prevalence of hearing loss in France 2009, 2012 and 2015 (Eurotrak 2015)



Source: EHIMA, 2015

In the last section of this study (cf. section 2.2), an estimation of the 2014 hearing loss prevalence by adult age group will be carried out on the basis of INSEE demographic data and hearing loss rates available in the 1998 survey "*Handicap-Incapacité-Dépendance*" ('*Impairment – Disability – Dependency*'). These rates were also considered as steady over time.

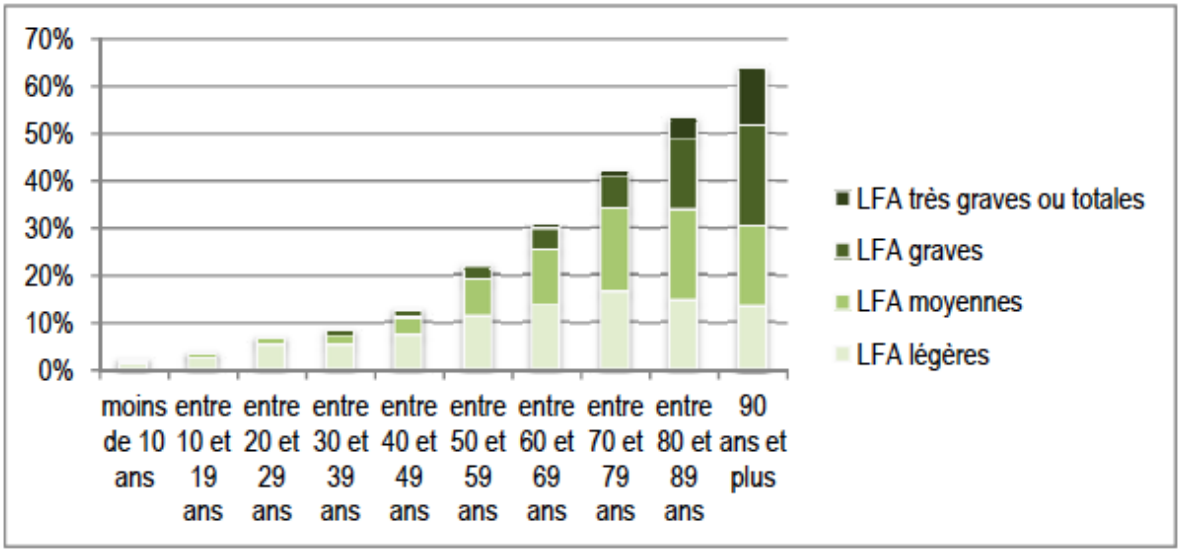
1.1.3 Main features of the population affected by auditive functional limitations

AFL concerned more men than women (17.2% and 15.1%), and are derived from professional status (exposure to noisy environments) or leisure habits (sound injury due to loud music or headphones). In the group of moderate to total AFL, the gap between men and women was more pronounced (10,4% and 7%)[8]. This gap appeared from the age of 40 years (whereas it appeared at an age of 50 years in the 1998 survey).

The link between the prevalence of AFL and age is very close: 10% of people aged 50 years and over were affected by moderate to total AFL, as shown in chart 2.

[8] This estimation is standardised by age, meaning that it relies on the hypothesis of a similar structure of male and female populations by age group.

Chart 2 – Prevalence of auditive functional limitations by age and severity



Interpretation: "moins de 10 ans" : younger than 10 years old; "entre 10 et 19 ans" : age ranging between 10 and 19 years – "LFA légères": slight AFL ; "LFA moyennes" : moderate AFL ; "LFA graves" : severe AFL ; "LFA très graves ou totales" : very severe to total AFL

Source: DREES, 2014

Not only does the prevalence of AFL increase with age, but from 60 years onwards the relative size of moderate to total AFL overtakes slight AFL : 59% of people suffering from moderate to total AFL were aged 60 years and older[9]. Moreover, starting from 80 years, AFL – all levels of severity inclusive – affects more than one out of every two individuals. If the age of occurrence for very severe to total AFL is always known, it remains unknown in the general case for the group of moderate to total AFL, as well as the causes of hearing loss, which are not specified in most cases. An advanced age is likely to be associated with more difficulties with social integration.

As regards the professional category (actual or former occupation), the prevalence of moderate to total AFL is variable: workers and farmers were more affected (+13%) than craftspeople, shopkeepers and company heads (+9%) or senior managers (+10%). Nevertheless, it isn't possible to interpret the direction of causality (impact of AFL on occupation or impact of occupation on AFL occurrence, except for farmers for whom an excess of risk due to working conditions is demonstrated)[10]. The presence of AFL seems to have an impact on qualification level or job occupation (InVS, 2015). However, job rates and unemployment rates are similar to national average rates, except when AFL is very severe or total. Moreover, for the working population, the search for multivariate demographic and socio-economic factors likely to explain the prevalence of moderate to total AFL only brings out the age, the sex and the level of qualification (particularly when the qualification is higher than a bachelor's degree)[11].

[9] This study most often focuses on the elderly category, given the greater severity of hearing troubles and the significant size of this population in hearing loss prevalence.

[10] Odds-ratio 1.49* (1.08-2.06): all age and sex being equal, the likelihood of being affected by moderate to total AFL for a worker or a farmer is 1.5 times greater than for managers and self-employed professionals.

[11] Cf. Haeusler and al. (2014), p.22 and following.

Compensation of hearing loss leads to hearing aid equipment (even to cochlear implants in some severe cases). However, the rate of people being equipped is substantially lower than the rate of prevalence for moderate to total AFL. It is convenient to analyse the main triggers of access to hearing aids, in order to later question the economic impact of hearing loss.

1.2 Access to hearing aids in France: an overview

Hearing aids ("*audioprothèses*") are a device allowing the wearer to receive, process and amplify sounds, which have to be adapted to the user's ability of understanding (perception) and tolerance. Thus, they are a medical device for individual use.

In order to highlight some approximations relating to the expenditure of the hearing aid sector, to the average price of a piece of equipment and to hearing aid access, several data sources have been cross-referenced. Moreover, the rules for social financing of hearing aids are featured, where public and private insurance coverage is associated with a large net out-of-pocket expense for adult HAs users. Finally, the provision of the equipment, combining the device and the service, is addressed in its specificity.

1.2.1 Public and private hearing aids expenditure in France

Hearing aid expenditure is neither directly estimated, nor at least released in published French health accounts or in the open database '*Eco-santé OCDE'*. Indeed, the expenditure for this item is comprises within the overall range of prosthesis (including hearing aids, orthopaedic braces and vehicles for impaired persons)[12]. Hence, an estimation is proposed on the basis of some available trend data, and then the expenditure is split up into both a volume effect – depending on the number of hearing aid users – and an average price effect.

1.2.1.1 Overall hearing aids expenditure

Overall hearing aid expenditure ranged around one billion euros in 2015, an estimation based on the previous data combined with the growth rate of sales, as well as the figures in the IGF-IGAS report (2015)[13].

Estimation of the overall expenditure for 2011

In 2011, overall hearing aid expenditure was estimated to be around 800 million euros by the *"Haut Conseil pour l'avenir de l'assurance maladie*" ('High Council for the Future of Health Insurance') HCAAM (2013b) and the Court of Accounts (2013)[14], with :

- 114 million euros funded by National Health Insurance ("*Assurance maladie obligatoire*", AMO) (around 14% of the overall expenditure);

[12] A difficulty which is underlined by the Court of Accounts (2013). As for the field of 'other medical devices' for individual use, it depicts 80000 different products (Court of Accounts, 2014).
[13] IGF: General Inspection of Finances. Cf. volume 2, form 8, p.59.
[14] Cf. p. 395, by deducting optics.

- 246 million euros funded by complementary health insurances ("*Assurance maladie complémentaire*", AMC) (around 31% of the overall expenditure).

Social expenditure presented a sustained average annual growth rate that was sustained at a rate of 11% between 1997 and 2009 (IGAS, 2010).

Estimation of the overall expenditure for 2012

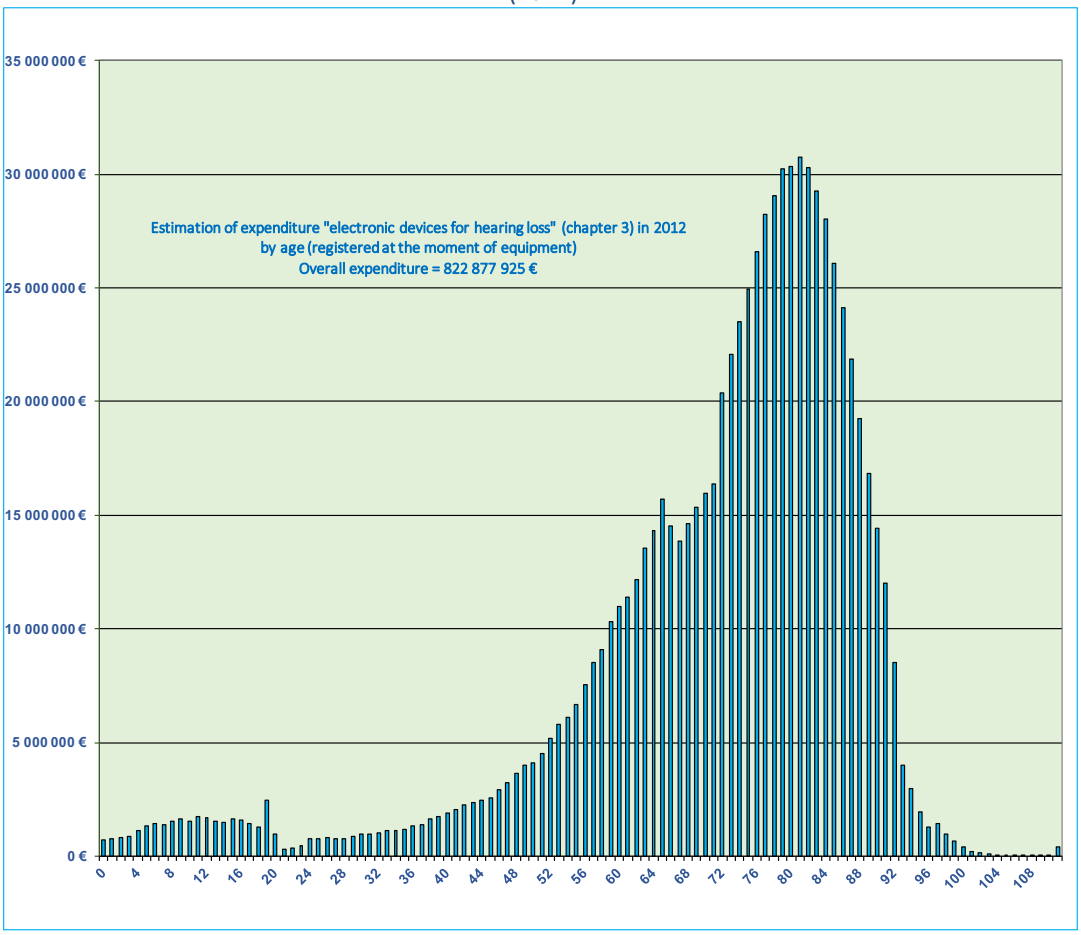
In 2012 (IGAS, 2014), overall hearing aid expenditure rose to 824 million euros, including:

- a reimbursable amount of 169 million euros (cf. infra);
- a reimbursable amount of 112 million euros covered by National Health Insurance (AMO) (a base rate for reimbursement of 65.5%, and a real rate of reimbursement of 13,6%);
- a gross out-of-pocket amount (including coverage of complementary health insurance AMC) of 711 million euros.

In addition to these overall estimates, the National Health Insurance data (database 'SNIIRAM) used by the French trade union of audiologists (UNSAF - "*Union nationale des syndicats d'audiprothésistes français*"), and members of the National Union of Health Professionals (UNPS, "*Union nationale des professionnels de santé*"), enable us to highlight the distribution by age of the hearing aid expenditure for 2012, then estimated to be 822 877 925 euros[15]. This distribution illustrates the strong concentration of reimbursed social expenditure for people aged 54 to 95 (chart 3).

[15] The gap between estimations – on the one hand IGAS (2014) and on the other hand UNSAF (Godinho, 2015a) – for 2012 data should be explained either by the different areas of inclusion for social expenditure in the SNIIRAM database (a non-exhaustive field at 100% depending on the inclusion or not of the different health care insurance funds) or else by the portion of hearing aid expenditure not presented for reimbursement. The Competitions Authority assess the amount of revenue to be 927 million euros in its 2016 public notice (without specifying a year of reference, which was probably 2014 or 2015).

Chart 3 – Distribution of the item “electronic devices for hearing loss” by age in SNIIRAM database (2012)



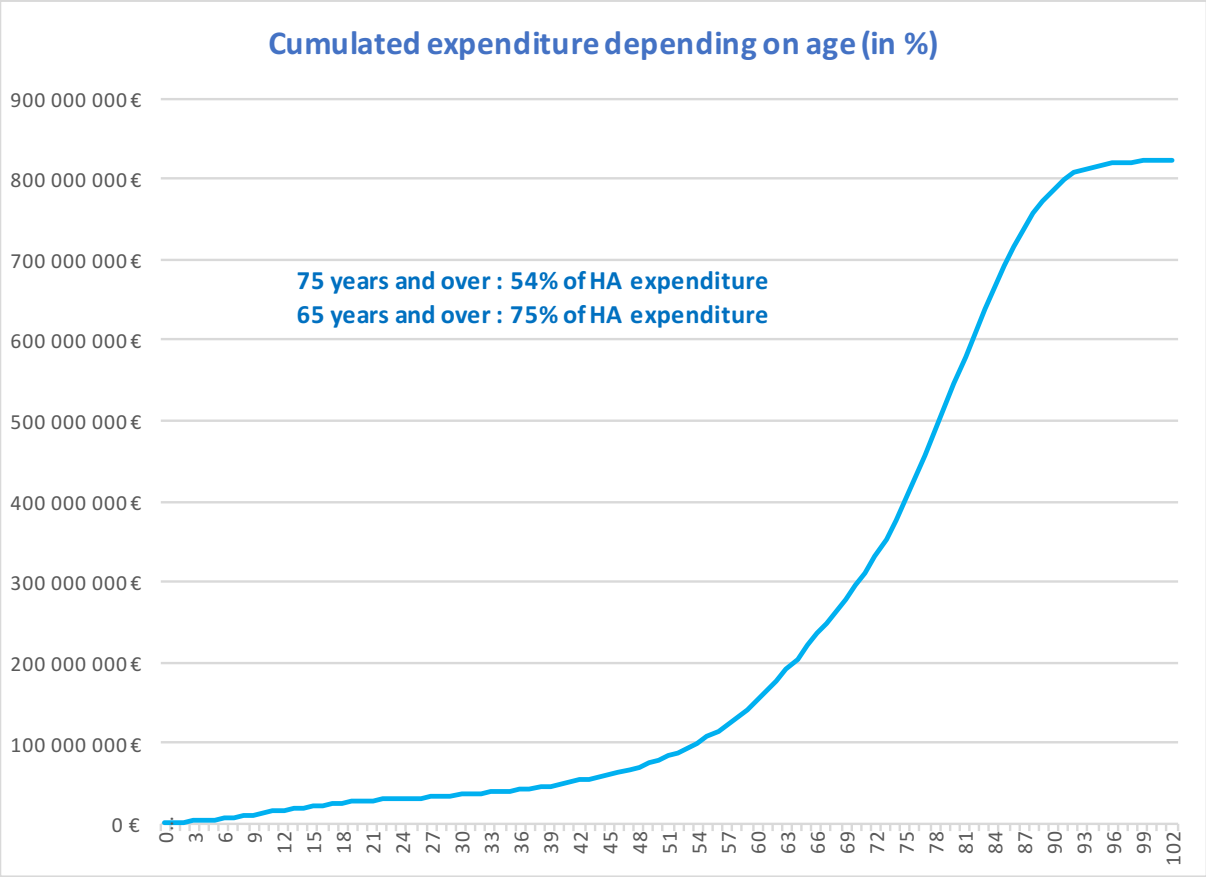
Source: Sniiram – data and chart UNSAF (2015).

Two shortages are visible in this distribution, interpreted by UNSAF as threshold effects due to coverage rules: the end of specific rights for younger people when they reach the age of 20 years; and the end of eligibility to collective contracts, well-known to be more generous, from the age of 65 years (cf. infra). The highest expenditure is observable at 81 years (around 31 million euros).

The cumulated expenditure clearly brings about delayed access to hearing aids, regarding the AFL prevalence data released by DREES (Haeusler et al., 2014). Indeed, older people over 65 represent three-quarters of the expenditure whereas people over 75 comprise more than half of the expenditure (54%)[16] (chart 4).

[16] As for UNSAF (2015), the noteworthy cumulated percentages are: 3.1% < age 20, 9.1% < age 50, 24.9% < age 65, 45.9 % < age 75.

Chart 4 – Cumulated expenditure by age, on item "electronic device for hearing loss" in 2012



Source: SNIIRAM – data and chart UNSAF (2015).

Finally, the main data relating to overall hearing aid expenditure are shown in table 7.

Table 7 – Summary table: overall hearing aids expenditure in euros depending on data sources

Year	Source	Overall HAs expenditure in euros	AMO (National Health Insurance)	AMC (Complementary health insurances)	Gross OOP
2011	HCAAM (2013b)	800 million	114 million (14%)	246 million (31%)	
2012	IGAS (2014)	824 million	112 million (13,6%)		711 million
2012	SNIIRAM (UNSAF 2015)	822,877,925			
2015	IGF-IGAS (2015)	1 billion			

Source: Authors on basis on available data

1.2.1.2 Estimations of the number of hearing aid users

Estimations of the number of hearing aid users in France vary according to the extrapolated data of surveys (decennial survey '*Handicap Santé*' 2008; Alcimed/DSS, 2011; biennial survey ESPS 2012; Eurotrak 2015).

Estimations of the 'Handicap-Santé' survey 2008

Following the 'Handicap-Santé' survey of 2008 (Haeusler et al., 2014), in 2008 access to hearing aids concerned 1,112,000 people (1.8% of the whole population, given that only 20% of people affected by moderate to total AFL wore hearing aid(s) – and were more frequently women and senior executives, all sex and severity levels of hearing loss being equal)[17]. However, the rate of hearing aid owners had increased by 7 points between 1998 (13%) – the year of the previous survey – and 2008: this could be explained by a better quality of hearing aid equipment.

Table 8 – Hearing aid equipment rate for people affected by moderate to total AFL

Age	Under 20	20-44	45-59	60-74	75 and over	Overall
			Equipment rate			
Moderate AFL		13%	8%	17%	31%	18,4%
Severe AFL		9%	8%	20%	30%	21,8%
Very severe to total AFL		25%	19%	26%	41%	33,5%
Moderate to total AFL	37%	14%	8%	15%	32%	20,4%
			Need for an equipment			
Moderate AFL		22%	28%	32%	41%	32%
Severe AFL		35%	45%	51%	51%	47%
Very severe to total AFL		32%	51%	63%	49%	51%
Moderate to total AFL	9%	26%	34%	38%	45%	37%

Source: DREES, 2014

Younger people aged under 20 (37%) are more often equipped with hearing aids than those aged 75 and over (32% against 21% in 1998), which can be explained, simultaneously, by a better social coverage of the former group and a better response to equipment in terms of its effectiveness (cf. infra). Also, it should be underlined that:

- Women are more often equipped than men among people aged over 60;
- Senior executives are more often equipped than workers, all levels of severity being equal (they are twice as likely to be equipped) and independent of any income effect (not significant in the survey);
- Impaired people are more often equipped than other people in the age group 60-74 years, due to French social coverage rules which distinguish impairment and old age (cf. infra);
- In the labour force, there is no significant difference between employed and unemployed people (despite the fact that the latter have lower incomes).

As far as the income effect is not perceptible on hearing aid access in the survey, this access seems to depend more largely on a socio-psychological effect (hearing aids are more discreet for women than for men), on a socio-cultural effect probably due to information (socio-economic class effect) and on the level of public and (above all) private coverage.

Estimations of Alcimed-DSS (2011) for the year 2009

The Alcimed-DSS survey established the following observations:

- 1.25 million French people are hearing aid(s) users (estimation based on trade union data), being 31.7% of the population eligible for hearing aids;

[17] The rate would be of 10.7% if the whole AFL had been taken into account.

- among hard of hearing people (6,300,000 people), half were eligible for hearing aid equipment;
- hence, there is notable room for improvement given the target of 3 million people (being 1,75 million people who need at least one hearing aid);
- the average age at first equipment is estimated to be 71, thus at a late age, as a consequence of a delay in the diagnosis followed by a delay in access. The gap between the perception of a decline in hearing and the purchase of a device is estimated in years[18].

Estimations of the biennial survey ESPS for the period 1992-2012

The biennial surveys "*Santé et protection sociale*" ESPS ('*Health and Social Welfare Survey'*) show a remarkable evolution in hearing aid access between 1992 and 2012[19] (table 9):

Table 9 – Evolution of the number of hearing aids owners from 1992 to 2012

Metropolitan France	A Hearing aids owners In % of total population	B Hearing aids owners aged 65 and over In % of total population	C Inhabitants Number	D Hearing owners Estimated number
1992	1,0	6,0	56 975 597	569 756
1993	1,1	7,0	57 239 847	629 638
1994	0,9	6,0	57 467 085	517 204
1995	0,9	5,5	57 658 772	518 929
1996	1,0	5,0	57 844 247	578 442
1997	1,2	5,8	58 025 989	696 312
1998	1,0	5,7	58 207 490	582 075
1999	nd	nd	58 397 788	nd
2000	1,0	4,9	58 677 406	586 774
2001	nd	nd	59 062 385	nd
2002	1,9	7,8	59 476 236	1 130 048
2003	nd	nd	59 893 870	nd
2004	1,5	7,1	60 303 631	904 554
2005	nd	nd	60 734 343	nd
2006	2,2	9,1	61 181 499	1 345 993
2007	nd	nd	61 597 486	nd
2008	2,3	8,6	61 965 052	1 425 196
2009	nd	nd	62 615 472	nd
2010	2,3	8,6	62 917 790	1 447 109
2011	nd	nd	63 223 158	nd
2012	**3,7**	**11,4**	**63 514 003**	**2 350 018**
AAGR	**6,8%**	**3,3%**	**0,5%**	**7,3%**

Source: Biennial survey ESPS, data Eco-Santé OCDE (available online February 2016).

[18] According to *Le Monde* 29 September 2009, access to hearing aids requires "seven years of reflection" (estimation based on the 'Ipsos' survey, June 2009). The Eurotrak survey for France 2015 estimates more precisely that 84% of people being equipped waited just under 6 years before accessing equipment and 43% waited between 3 to 6 years.

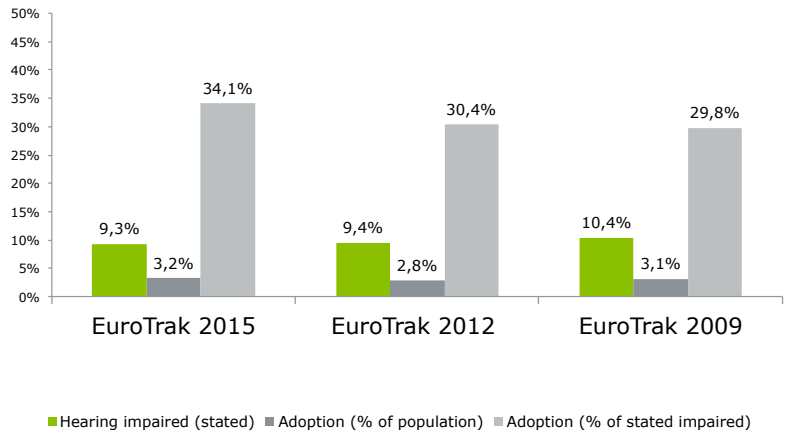
[19] The ESPS survey collects data from a panel sample of 8000 ordinary households (20,000 people) and is considered as representative of 97% of the French metropolitan population.

- The proportion of hearing aid users has risen from 1% to 3.7%, namely an average annual growth rate of 6.8%;
- The proportion of hearing aid users older than 65 years has grown from 6% to 11.4%, namely an average annual growth rate of 3.3%. At the same time, the rate of these people declaring hearing trouble rises to 23%;
- Taking into account these latter observations, the rise in access to hearing aids appears to be pushed upwards by people younger than 65 years, rather than by those over 65, indicating earlier access to hearing aids;
- The estimated number of hearing aid users has increased by 7.3% per annum over the entire period, growing from 569,756 people in 1992 to 2,350,018 people in 2012. This average annual growth rate is due to a combination in the growing number of people being equipped and demographic growth of 7.6% in the period 2002 to 2012;
- In 2012, there is probably an overestimation in the number of hearing aid users' numbers (2.35 million people according to the survey). This presumption of overestimation is reinforced when compared to other available recent data (cf. infra table 18). According to our estimation, the number of hearing aid users ought to be about 1. 8 million people in 2012.

Estimations Eurotrak 2015

The Eurotrak survey estimates the rate of hearing aid access at 34.1% of the hearing impaired population in 2015 and shows also that older people aged over 65, affected by hearing impairment, are equipped at 42% (23.2% for the age group 45-64 and 29.5% for people younger than 45 years).

Chart 5 – Evolution of the rate of hearing aid access relative to hearing loss prevalence (2009, 2012, 2015) Eurotrak data

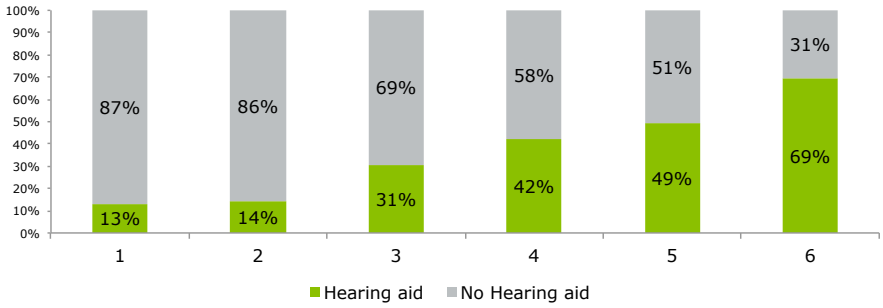


Source: EHIMA, 2015

70% of people being equipped have got a binaural device (both ears). Moreover, access is as great as hearing loss severity is severe (chart 6)[20].

[20] Severity is assessed on the basis of a hearing loss level that depends on: monaural or binaural equipment, grade of hearing loss (moderate to severe), score on APHAB scale, and degree of difficulty to follow a

Chart 6 – Rate of hearing aids access relative on hearing loss severity (Eurotrak)



Source: EHIMA, 2015

Reference values

According to the variability of estimations (cf. table 10), it seems to be relevant to take on an access rate ranging between 30% to 35% of the population affected by disabling hearing loss[21]. Reader's attention should be drawn to the meaning of the difference between the rate of hearing loss prevalence and the rate of people being equipped with hearing aids: this difference doesn't fit with the population that would be both not equipped and able to be equipped. For different reasons relative to feasibility of equipment, to the relevance of a hearing compensation, to possible therapeutic options for severe cases (i.e. cochlear implant), or else to social and psychological factors (rejection of hearing aids), the access to hearing aids is foreseeable only for a fraction of hearing impaired people. It is usually considered that the population eligible for hearing aid equipment represents half of the impaired population. This reference target, central in this report, is highlighted further (cf. 1.2.2.3).

conversation in a noisy background without hearing aid equipment. This estimation leads to 6 groups of identical size (16,67%).

[21] The IGAS (2014) estimates the number of impaired people to be 7 million, of whom 15% are equipped. The "*UFC-Que choisir*" (French Consumers Association – periodical 'What to Choose') (2015) estimates this number at 6 million, with 25% equipped. These rates of equipment are among the lowest values in the whole set of surveys.

Table 10 – Summary of estimated rates of hearing aids access in the literature and surveys

Year	Survey and HL criteria	Access rate to equipment	Prevalence rate of hearing loss
2008	Handicap Santé (disabling hearing loss)	15,8%	11,2%
2008	Handicap santé (moderate to total AFL)	20,4%	8,6%
2008	ESPS	23,0%	10,0%
2009	Eurotrak	29,8%	10,4%
2009	Alcimed-DSS	31,7%	10%*
2010	ESPS	23,0%	10%*
2012	Eurotrak	30,4%	9,4%
2012	ESPS	37,0%	10%*
2015	Eurotrak	34,1%	9,3%

* Assumption

Source: Authors on basis of different survey data.

Another way to estimate this rate of hearing aid access is to base numbers on the quantity of devices sold (according to the "*Syndicat national de l'industrie et des technologies médicales*" SNITEM – 'National Union of Medical Industry and Technologies') during the last 6 years (the median lifespan for equipment is 6 years according to the Eurotrak survey 2015 for France), and then to consider the share for binaural equipment (70%, same source). Thus, it is possible to estimate the number of wearers of hearing aids, by assuming that the devices bought in the last six years have as yet to be renewed, giving 2,041,075 hearing aid owners. Given a rate of hearing loss prevalence of 10% in 2012, the access rate would then be about 32,6%[22].

Hence, this study is based on a reference rate for hearing aid access ranging between 30 to 35% of the hearing impaired population.

1.2.1.1 Estimations of the average price of a hearing aid

According to the SNITEM (2015), hearing aid sales have followed a dynamic trend for the 20 years from 1994 to 2014:

[22] It would be interesting to estimate retrospectively and prospectively the progression of the rate of hearing aids owners on the basis of SNITEM sales data, on the demographic structure of population and life expectancy, on the rate of device renewal (median of 6 years) and the rate of new purchasers and on the binaural rate of equipment. However, this estimation would be dependent on several assumptions (stability of device duration and of rate of binaural equipment and, for the forecasting, stability of average annual growth rate for sales, stability of the renewal time occurrence, stability of the rate of diffusion related to acceptance, forecast of the noise exposure impact for young generations). This longitudinal analysis would require the design of several scenarios that goes beyond the scope of this study.

Table 11 – Estimation of sales for hearing aids between 1994 and 2014

Year	Number of sold devices	Rate of growth
1994	179 956	nd
1995	181 693	1,0%
1996	193 481	6,5%
1997	203 442	5,1%
1998	227 610	11,9%
1999	238 815	4,9%
2000	268 248	12,3%
2001	275 297	2,6%
2002	290 090	5,4%
2003	321 998	11,0%
2004	351 773	9,2%
2005	364 647	3,7%
2006	381 934	4,7%
2007	407 796	6,8%
2008	435 884	6,9%
2009	463 118	6,2%
2010	482 155	4,1%
2011	518 045	7,4%
2012	519 994	0,4%
2013	559 260	7,6%
2014	597 543	6,8%

Source: UNSAF-SNITEM, 2015

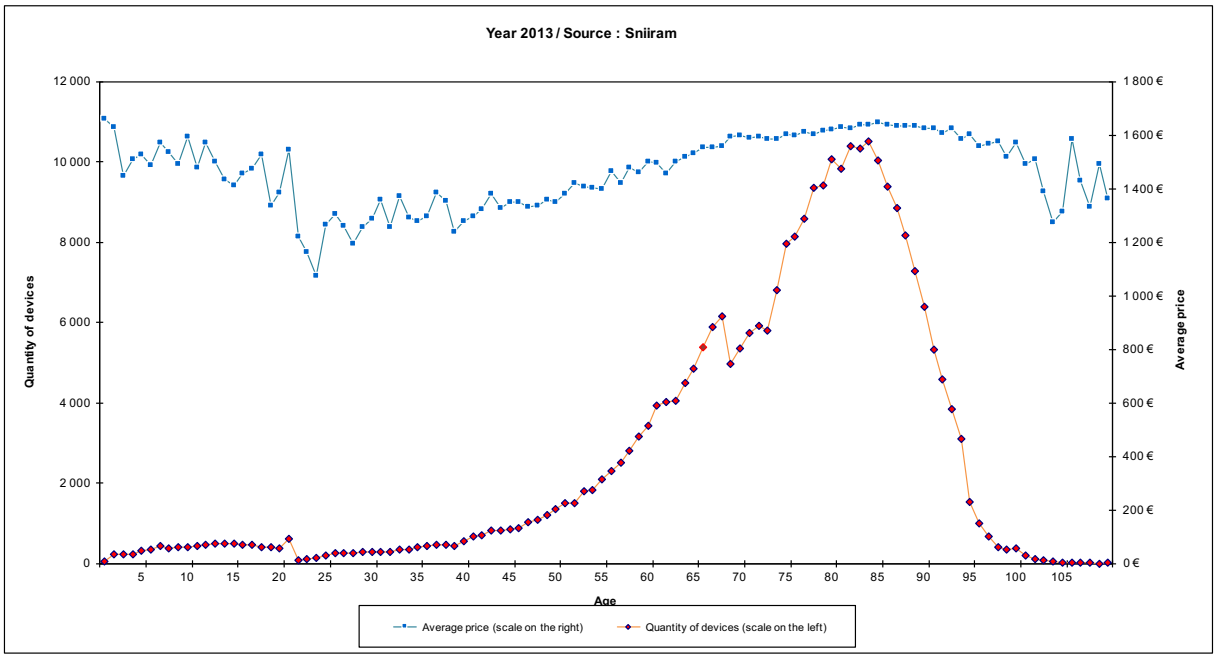
If we consider the previously estimated overall expenditure, which ranged from 822,877,925 euros to 824 million euros in 2012, and the number of hearing aids that were sold in the same year - 519,994 -, the average price per unit ranges from 1 582.5 to 1584.6 euros including VAT in 2012[23].

Estimations of UNSAF (2015)

Based on the SNIIRAM database for the year 2013, UNSAF's estimations amount to an average price of 1456.35 euros inc. VAT for people aged over 20. They also highlight the fact that the price level depends closely on age and that this price is above the average value after the age of 55 (and the threshold effects previously underlined remain visible, due to the financing rules for the device).

[23] The value added tax ("*taxe sur la valeur ajoutée*", TVA') applied on the device and batteries is of 5.5%.

Chart 7 – Average price as a function of age in in 2013



Source : Sniiram – data and chart UNSAF (2015).

The distribution of average prices by age shows that a hearing aid is more expensive for older people aged 65 and over (1,560.83 euros inc. VAT), then for younger people under 20 years old (1,503.60 euros VAT) and for people aged between 20 and 64 (1,349.51 euros VAT).

Table 12 – Average VAT price for a hearing aid by age groups in 2013

Age	Under 20	20-64	Over 64	Overall population
Average price	1,503.60€	1,349.83€	1,560.83€	1,465.37€
Number of people	8,064	59,458	218,271	285,793
Number of devices	16,054	100,312	339,435	455,801
Binaural Rate	99.08%	68.71%	55.51%	59.49%

Source: SNIIRAM – data and table UNSAF (2015).

Other estimations in the grey literature

The grey literature captures in general an average unit price of 1,600 euros inc. VAT in 2009 (Alcimed-DSS, 2011), or 1,550 euros inc. VAT in 2014 (Autorité de la concurrence, 2016) or 1,535 euros inc. VAT in 2011 (estimation of the National Health Insurance CNAMTS that has been used by the Court of Accounts (Cour des comptes, 2013), the IGAS (2014) and the IGF-IGAS (2015)), being around 3,070 euros inc. VAT for both ears[24].

[24] These estimations don't include the technical cost of maintenance (batteries etc.).

These estimations do not depend on the year of the study, since it must be noted that prices have remained quite steady over time, or have even contracted, given the evolution of both general inflation and revenues. Indeed, the average price of a digital hearing aid has stayed very steady between 1998-2000 and 2012, according to the National Council of Consumption ("*Conseil national de la consommation*", 2000): at this date, the price of a digital hearing aid ranged from about 9,000 francs VAT (1,372 euros) to 10,000 francs VAT (1,525 euros) (including the device and the service)[25]. Thus, if the level of the price is certainly a factor hindering access to equipment, the evolution of the price in itself cannot be supposed to add as a cumulative factor.

The French sales structure is characterised by a concentration on middle-market and up-market hearing aids[26]. According to Alcimed-DSS (2011), 80% of sales are concentrated in these two market sectors (table 13)[27].

Table 13 – Average price as a function of the hearing aid's market sector in 2009

Device Line	CMU-C	Downmarket device	Middle market device	Upmarket device
Price inc. VAT in euros (one ear)	700*	600-1100 (average 1000)	1100-1700 (average 1500)	1600-2200 (average 1950)
Market share (2009)	2-3%	15%	50%	30%

CMU-C in March 2016

Source: Authors on basis of Alcimed-DSS (2011) – Prices VAT

The dynamism of the hearing aid market (average annual growth rate: 6.2% between 1994 to 2014) is largely sustained by the growth in users aged over 60. Given that hearing loss prevalence due to presbycusis becomes marked from 55 years and it would then generate 95% of hearing loss (Alcimed, 2011). The French market is often considered opaque and not greatly competitive with regards to manufacturers or distributors[28]. According to the Court of Accounts (Cour des comptes, 2013), this opacity is largely due to a failure in collecting information within public authorities (the "*Comité économique des produits de santé*" CEPS or

[25] *Le Monde*, 16 May 1996, stated that innovative digital hearing aids entering the market were sold at a price of 12,000 francs (1,830 euros) per unit, while other models were being sold at an average price of between 6,000 francs (914 euros) to 7,000 francs (1,067 euros). Four year later, *Le Monde*, 12 March 2000 related an average scale of prices for digital hearing aids from 9,000 francs (1,372 euros) to 12,000 francs (1,830 euros) with a market penetration of 30%. At this time, the reimbursement base was still fixed at 1,310 francs (199.7 euros), linked to a coinsurance rate of 65% for each reimbursed ear.

[26] There are four main lines of device, A, B, C and D. If these ranges and classifications made sense when designed (a higher range corresponding to more complex and advanced technology, referred to as D devices), the fast rate of innovation has pushed highly technological devices into the downmarket or middle market range, without reclassification. Incidentally, more than 94% of 2014 sales are classified in the D range.

[27] Following estimations of the IGAS (2014), the average price of downmarket devices ranged from 700 to 800 euros. 90% of purchases were made on upmarket devices at an average price of 1,900 euros.

[28] There is an international oligopoly of six manufacturers comprising 80% of worldwide market share, being Sonova (24%), Siemens (22%), William Demant (22%), Starkey (24%), GN Resound (12%), and Widex (10%) (According to several sources, see for example Cour des comptes , 2013, p. 397). The oligopolous market can be explained by both a high value technological investment and a relatively reduced market for sales. The factory price excluding tax varies between 200 euros and 800 euros, hence a net margin for manufacturers from 5% to 13%.

'Economic committee of health products' itself not having available sales statistics for medical devices). The topics of competition, market characteristics, product differentiation strategies, hearing aid distribution networks and sector regulations go beyond the framework of this study but the interested reader should refer to recent studies by the Court of Accounts (Cour des comptes, 2013 and 2014), by the Directorate of Social Security ("*Direction de la sécurité sociale*" - DSS, 2011), the IGAS (2013 and 2014), the IGF-IGAS (2015), and by the Competition Authority (Autorité de la concurrence, 2016)[29].

Table 14 – Estimations summary of the average price for a hearing aid in the literature

Year	Source	Estimated average price for a hearing aid in euros
2009	Alcimed-DSS (2011)	1600
2012	SNIIRAM UNSAF (2015) and SNITEM (2015)	1583
2012-2013	CNAMTS (Court of Accounts, 2013; IGAS 2014; IGF-IGAS 2015)	1535
2013	Non exhaustive SNIIRAM UNSAF (2015)	1465
2014	Competition Authority (2015)	1550

Source: Authors on basis of available data

If valuations of the average price for one hearing aid vary between sources, they converge to 1,535 euros inc. VAT per unit, which is the French reference value in this study.

1.2.2 Financing hearing aids

For the most part, access to hearing aids concerns older people and impaired people. If social financing is quite 'generous' in some particular cases (people younger than 20, the blind, beneficiaries of complementary universal health insurance ("*couverture maladie universelle complémentaire*"- CMUC), and some impaired persons), it is usually very low in relation to the price level of hearing aid equipment. According to the HCAAM (2008), 87.5% of hearing aid owners request the social coverage offered by the National Health Insurance[30].

1.2.2.1 Financing rules for hearing aids as either technical support or medical devices

Hearing aids belong to the 'technical support' category, which is defined for beneficiaries of impairment compensation allowance ("*prestation de compensation du handicap*" - PCH) as "*all technical apparatus or systems adapted or specially designed to compensate an activity limitation met by the person because of impairment, and acquired or rented by the impaired person for his own use*"[31]. This definition is retained more largely by the IGAS (2013), for lack

[29] The Competition Authority has proceeded to Public Inquiry in February 2016 in order to highlight the presumed failures of the market, not least because of the survey by the UFC-Que choisir « *Audioprothèses : un marché verrouillé au détriment des malentendants* » ('Hearing aids : a closed market to the detriment of hard of hearing people', released in September 2015.

[30] At this time, for 400,000 sold devices, 350,000 would have led to a reimbursement request. However, no further estimation of this share was available for recent years.

[31] See appendix 2-5 of the Social Action and Family Code ("*Code de l'action sociale et de la famille*" (CASF)).

of a similar definition for beneficiaries of the personalised autonomy subsidy ("*allocation personnalisée d'autonomie"*, APA).
Such a pitfall is revealing – as underlined by the IGAS – of the great confusion surrounding the rights and waiting periods involved in financing technical support, depending on recipients' classification into illness, impairment or old age (this differentiation of needs, rights or status – illness, invalidity, impairment, dependency - is particular to France). This confusion is reinforced by the multiple financing bodies in case of impairment and by the variation in rights depending on the area of residence.

Furthermore, hearing aids are not only technical supports but are also medical devices ("*dispositifs médicaux*", DM), and thus relate to healthcare, and to the list of reimbursable products and service provision ("*Liste des produits et prestations remboursables*" - LPPR) defined by the National Health Insurance[32]. However, registration in the LPPR is not linked to an upper price limit (unlike most medical devices) and the gap between prices and tariffs is remarkably wide (CEPS, 2015)[33]. The juxtaposition of definitions, public bodies and rights has finally resulted in a lack of management of the access to technical supports, to high costs due to organisation and the risk of errors, and to inequalities between customers whose level of information about accessibility varies greatly.

1.2.2.2 Public and private financing rules for hearing aid equipment

Coverage by the National Health Insurance

As of February 2016, the National Health Insurance covers, for standard cases (i.e. people older than 20 years and/or no blindness impairment[34]), 60% of the LPPR tariff for a hearing aid, fixed at 199.71 euros, that is 119.83 euros per unit[35]. This reference tariff includes not only the device itself, but also the accessories, the adaptation and prosthetic education by the

[32] Article L. 5211-1 of the Public Health Code which imposes norms, such as the CE mark by the manufacturer (article L. 5211-3).
[33] "Fixing a ceiling price for sales implies, however, if need be, the resolution of the question of any surcharge billed in return for/against services or accessories exceeding the definition of the reimbursable product or service specified by the list. In particular, this is the case in the external prosthesis or orthotics sectors, where patients ought to ask for, and suppliers ought to offer, technical or aesthetic accessories, but not only that. For example, in the field of hearing aids for very young people, professionals argue that the gap between prices and tariffs allows for payment for audiologists whose intervention is needed to adapt the equipment for their patients, and could, depending on the case, represent a great number of consultations for very young people or multi-impaired persons. Indeed, the resulting out-of-pocket sum was mostly reimbursed either by the CMU-C, or by complementary insurances and in other cases by means of regional or local assistance bodies, and was often requested by audiologists themselves. The difficulty, even the impossibility, in these situations to determine a bounded price of sale according to rational references and existing finance possibilities have led the Committee to postpone the fixation of a ceiling price for sales for these hearing aids that would be superior to the tariff", CEPS (2015), p.142.
[34] In these particular cases, technical support equipment is reimbursed at a coinsurance rate of 60% for prices ranging between 900 and 1,400 euros, depending on the device classification. In the case of a chronic disease or 'long-term affliction' ("Affection de longue durée", ALD) or in the case of invalidity allowance, the rate of reimbursement is 100% of the LPPR tariff. Cf. www.ameli.fr accessed 24 February 2016.
[35] The reimbursement rate dropped from 65% to 60% in 2011.

audiologist, as well as the follow-up which has to be planned on an indicative basis for the 3rd, 6th, and 12th month and then twice a year thereafter. Renewal of the equipment is possible at any moment, only one limit is imposed on CMU-C beneficiaries (cf. infra). A fee for annual maintenance is also covered (rising to 21.96 euros per unit, that is 60% of the LPPR tariff of 36.59 euros) on evidence payment receipt (batteries, spare parts, or for repairs with labour included)[36].

Coverage by complementary insurances (apart from CMU-C)

According to Garnero and Le Palud (2014), the coverage of the cost of hearing aids by complementary health insurance is very variable, depending on the nature of the contract (individual or collective) and on the type of insurance (mutual fund, provident society or private for-profit insurance). In general, the complementary health insurance bodies ("*organismes complémentaires d'assurance maladie*", OCAM) cover not only the residual co-insurance (40% of the reference tariff) but also take on a supplementary financing (for 89.3% of OCAM). This supplementary funding is more often insured by collective contracts (94.7%) and by provident societies (98.6%) than by individual contracts (85.2%) (table 15).

Table 15 – Complementary insurance reimbursement for hearing aids in 2010
in % of beneficiaries (covered people)

Types of CHI and types of contract		Not any refunding/RT	Partial refunding/RT	Total refunding/RT	Extra refunding / RT	Overall
Mutual funds	Collective contracts	4.3	0	9.9	85.8	100
	Individual contracts	2.1	0.8	7.8	89.3	100
	Overall contracts	***2.7***	***0.6***	***8.4***	***88.3***	***100***
Provident societies	Collective contracts	0.7	0	0	99.3	100
	Individual contracts	0	1	5.9	93.1	100
	Overall contracts	***0.7***	***0.1***	***0.6***	***98.6***	***100***
Private for-profit insurances	Collective contracts	0	0	0	100	100
	Individual contracts	2.3	3.3	19.3	75.2	100
	Overall contracts	***1.5***	***2.1***	***12.4***	***84.1***	***100***
Overall insurance bodies	Collective contracts	1.8	0	3.5	94.7	100
	Individual contracts	2.1	1.5	11.2	85.2	100
	Overall contracts	***2***	***0.9***	***7.9***	***89.3***	***100***

RT : reference tariff of National Health Insurance (200 euros) associated with a coinsurance rate fo 60%

Source: DREES, 2014

In 2010, the complementary health insurance bodies (OCAM) declared an average reimbursement rate of 30.5% for 2009 against a reference price of 3,000 euros inc. VAT relative to two hearing aids (914 euros, at 457 euros per unit), with collective contracts offering more generous coverage (41.7% in comparison to 22.1% for individual contracts). Half those insured people received less than 851 euros for two hearing aids (the median value for reimbursement equal to 28.4% of the reference price). Provident societies offered the best coverage and private for-profit insurance the weakest (table 16).

[36] Spare parts listed in the LPPR may give rise to extra reimbursement.

Table 16 – Distribution of the reimbursement for a pair of hearing aids in 2010
(reference amount for two numerical devices: 3000 euros VAT)

Types of CHI and types of contract		Mean	First quartile	Median	Third quartile
Mutual funds	Collective contracts	1 032	539	939	1 398
	Individual contracts	800	440	799	1 020
	Overall contracts	***865***	***445***	***840***	***1 039***
Provident societies	Collective contracts	1 487	1 138	1 538	1 997
	Individual contracts	777	578	739	1 138
	Overall contracts	***1 413***	***939***	***1 500***	***1 937***
Private for-profit insurances	Collective contracts	1 142	939	1 198	1 338
	Individual contracts	338	160	300	352
	Overall contracts	***626***	***240***	***390***	***1 038***
Overall insurance bodies	Collective contracts	1 252	790	1 138	1 737
	Individual contracts	662	260	640	976
	Overall contracts	***914***	***350***	***851***	***1 220***

Source: DREES, 2014

Finally, after public and private coverage (AMO and AMC) and on an average amount of 3,000 euros for two hearing aids, the net out-of-pocket sum for the owner would be either 1,846 euros (923 euros per ear)[37] starting from the mean reimbursement value, or 1,909 euros (954.5 euros per ear) starting from the median reimbursement value . This estimation takes into account the distribution of beneficiaries by type of insurance and by type of contract[38].

This estimation of AMC coverage is slightly higher than those found in the literature:

- 330 euros per ear for the Court of Accounts (Cour des comptes, 2013);
- 395 euros per ear for the IGAS (2014);
- 300 to 400 euros per ear in Alcimed-DSS (2011).

Thus, it is possible that OCAM have slightly increased the coverage rate, which can be interpreted as the effect of competition on contracts (but the "adverse selection" effect limits the relevancy of this explanation) or as a "forced" role in risk management by the withdrawal of National Health Insurance on this item. However, complementary insurance remains very weak for optics (68%) or dental care (38%)[39].

[37] Calculation: 3000 euros minus 240 euros (AMO) minus 914 euros AMC.

[38] Adverse selection refers to a situation in economic theory according to which if insurances offer better coverage for goods that are associated with higher risk (here, hearing aids associated with older age), they will capture the people likely to have other health troubles, and then they capture adversely high risk people. Moreover, in the table 19, collective contracts represent 42.7% of those insured. Their distribution is of 66.6% in mutual funds, 3.7% in provident societies and 29.6% in private for-profit insurances. Estimations of mean and median reimbursement take into account this distribution of those insured between the three different types of complementary insurances and the different types of contracts (collective or individual). Hence, these are weighted estimations. Moreover, quartile analysis shows that 25% of those insured are reimbursed at most for 350 euros for two ears, whereas 25% of them are reimbursed at least 1,220 euros.

[39] Data HCAAM, 2013b, p. 111.

One consequence of this differentiation between collective and individual contracts is the evident phenomenon of the high take-up of hearing aids just before leaving collective contracts by people reaching retirement age, whence the shortage effect previously shown. Indeed, older and retired people are financially penalized by the loss of social rights based on working status.

Coverage for the CMU-C beneficiaries

Audiologists are bound to offer hearing aid equipment suitable for CMUC beneficiaries within the limits of applicable tariffs, which were revalued in 2014 in order to reflect upgrades in medical devices for individual use (Cour des comptes, 2015). For a ceiling price of 700 euros per ear[40], the CMU-C beneficiaries are allowed one or two C-class hearing aids every four years, which the audiologist must be able to supply at this price. This revision of the reference tariff for this population should significantly reduce the adverse effects of the previous system (the equipment of the other ear postponed until two years later, or even the withdrawal of care by the audiologist)[41].

Coverage for the beneficiaries of PCH and APA

In the case of impaired persons, the PCH allows for an additional reimbursement allocation fixed by ministerial decree at a ceiling of 600 euros for a middle market or up-market device (C or D) in cases of severe impairment[42]. Variable allocations are likely to reduce the net out-of-pocket amount, and may even lead to over-reimbursement. In contrast, the assessment of elderly dependency does not allow, in most cases, for any supplementary APA (because of an overloaded help plan, the unsuitability of the autonomy grid AGGIR, or lack of awareness of the field).

Finally, it is arduous to estimate the real value of financial subsidies, and requires better knowledge of equipment life span. The entire statement of the IGAS (2013) is of a strong inequity in access and rights, and is as follows : " *for the same impairment or the same deficiency, older people in dependency and impaired people do not have, at this time, an equivalent access to technical support equipment*" and, among the latter, hearing aids are brought to the forefront of this criticism, since "*it is for this type of support equipment that the elderly declare their technical device needs to be the less well satisfied*"[43].

[40] Current reimbursement rule in February 2016, www.ameli.fr. Reimbursement for two devices is then guaranteed at a price of 1,400 euros by the CMU-C. Reimbursement levels are highest for people aged under 20 years or in cases of cumulative hearing loss and blindness.

[41] Before this tariff revision, the CMU-C beneficiaries were offered a total reimbursement of 443.63 euros for only one ear, the other ear being reimbursed at the reference tariff, so there was an observable gap in two-ear equipment and a low performant access to hearing aids.

[42] 16% of people with moderate to total AFL benefit from administrative recognition likely to be associated with an additional allowance (Haeusler et Mordier, 2014).

[43] p.5, IGAS (2013).

1.2.2.3 Estimations of out-of-pocket payment and healthcare renouncement

Estimations of out-of-pocket payment (OOP)

Gross out-of-pocket (or out-of pocket before AMC)

Apart from optical devices, hearing aids represent, in the field of medical devices, the greatest proportion of gross OOP payment before complementary health insurance intervention, representing 40% of the gross OOP payments (CESE, 2015).

As shown previously, the National Health Insurance (AMO) covers 120 euros per adult ear, independently of the apparatus class: this sum includes the service of the audiologist and VAT at 5,5%. In 2011, if one uses the study reference price – based on the Court of Accounts (2013) estimate of 1,535 euros per hearing aid - the gross OOP payment rises to around 1,400 euros per item, namely a gross OOP payment of 91%, or even 97% for an upmarket hearing aid. This gross OOP payment remains high in particular cases (younger people under 20 years old, and the blind) that represent 5% of hearing aid owners (the gross OOP payment varies from 54% to 59%).

Such a situation raises questions. It is due to the base for reimbursement being frozen since 1986, when hearing aids were obviously less efficient and when they were implicitly classified as "low risk" and a minor medical service, resulting in social reimbursement funding (AMO) of 6% to 9% of the device. It is also due to the withdrawal of National Health Insurance (AMO) in relation to the role of complementary health insurances which played a greater financing role, but also created more inequalities in the system (optional purchase, and differentiation of contracts). Finally, it is also due to the wait-and-see attitude of public authorities, and particularly to the "*paralysis of the reviewing of generic lines*" of the LPPR, which has the effect of "*penalising many patients as well as manufacturers who propose innovative solutions*"[44]. In any case, tariffs have not been reviewed for more than 10 years[45]. However, one noteworthy advance in 2002 was made with the adoption of reimbursement for stereo devices (while only one mono device was reimbursed before), resulting in strong growth for this item in the same year[46].

[44] Cour des comptes (2013), p.407. Thus, an examination of hearing aids in 2006 was planned by a decree of July 2005, but this opinion was only given in 2008 by the 'commission for products and benefits assessment' ("Commission d'évaluation des produits et prestations" – CEPP-, today CNEDIMTS since 2009) which proposed a new classification and a revision of technical prescriptions, a proposition which has not been followed by any obvious results at the time of this report. The main recommendations of the CEPP were: prescription supervision by an ENT specialist; a minimum real-life probationary period of 15 days for the prosthetic; standardised feedback to be given to the prescriber post-equipment; a 5-year, non-curtailable period before a new reimbursement, except when supported by the prescriber; classification based on the impairment level with a minimal requirement for technical performance by digital hearing aids. However, the CEPP maintained, given the literature, the generic prescription and did not discuss the indivisible character of the device and the performance of the provision.

[45] Cour des comptes, 2014, p. 311.

[46] Decree of 23 April 2002. Cf. HCAAM (2008).

Net out-of-pocket payment (OOP) (or out-of-pocket payment after reimbursement by AMC)

Despite the improvement in hearing aid reimbursement by complementary health insurances (AMC) and despite the positive evolution of the system for CMU-C beneficiaries, there remains weak coverage for those insured in this field**.** Depending on the policy holder's situation, and in particular regarding his/her complementary insurance contract, the net OOP payment is likely to be high, around 62% after coverage of AMO and AMC (8% + 30%)[47], and ranging on average from 45% for a downmarket device to 72% for an upmarket device, given that this range rises relative to the lower price of the downmarket device and the higher price of the upmarket device, the nature of the complementary insurance and the type of contract (table 17).

Table 17 – Estimation of the net out-of-pocket sum
as a function of the average or the median reimbursement by complementary insurance (AMC)

Device Line	CMU-C*	Downmarket device	Middle market device	Upmarket device	Average study's reference prices
Price inc. VAT in euros (one ear)	700	600-1100 (average 1000)	1100-1700 (average 1500)	1600-2200 (average 1950)	1535
OOP/ AMC mean reimbursement	0	23-523 (423)	523-1123 (923)	1023-1623 (1373)	958
OOP/ AMC median reimbursement	0	54-556 (454.5)	556-1155 (954.5)	1054-1655 (1404.5)	989.5

Source: Authors on basis on Alcimed-DSS data (2011), DREES data (2014) and the reference price of the study

On the basis of this study's reference price, the expense for an adult covered by a complementary health insurance policy apart from CMU-C rises to an average of 950 euros per ear. In the literature, the rough estimates are[48] :

- 1,040 euros/ear (Alcimed, 2011);
- 1,100 euros/ear for the Court of Accounts (Cour des comptes, 2013);
- 1,000 euros/ear (HCAAM, 2013);
- 940 euros/ear for the IGAS (2014).

The presumptive evidence of the weak public and private coverage of hearing aid expenditure is the rate of healthcare renunciation, which can take the form either of a delay in access to care regarding needs and/or of social inequalities in access to hearing aids (depending on the socio-economic category, the status of the need (illness, impairment, dependency), the ownership of complementary health insurance and its type). The literature does not provide a concrete estimate for care renunciation due to inability to pay, because the withdrawal of care access is the result of several factors: financial, psychological, and lack of information. It would be incorrect to use the rate of access to hearing aids to directly deduce the renunciation rate due to inability to pay.

[47] Estimated shares based on a hearing aid priced at 1,535 €, minus 120 € AMO, minus 457 € AMC following the previous data of the DREES (2014).
[48] No estimation exists for OOP impact on the household budget, given the occasional character of the purchase.

The proportion of people eligible for hearing aids is usually taken at 50% of the hearing impaired population. There are several ways to demonstrate its relevancy:

- first, by referring to the Alcimed-CNSA (2009) study which gathered expert recommendations in order to determine this reference rate of 50%;
- by studying the survey data from 'Handicap-Santé' 2008:
    - using the direct approach of hearing loss (cf. table 3): in this, 1.8% of the whole population declares themselves to be hearing aid users, 3.2% declare a need to use hearing aids without owning one, thus 5% of eligible people declaring for a hearing loss prevalence of 11.2%. This means that 44.6% of hearing impaired people are eligible to hearing aids (5%/11.2%);
    - or by the indirect approach of moderate to total AFL (cf. table 8): 20.4% of this population use hearing aids, 37% declare a need without owning one, namely 57.4% of the population with disabling hearing loss eligible to hearing aids;
- by analysing the access rate in countries where this access to hearing aids is free (complete financial coverage of the device), as in Denmark (cf. section 1.3.1): the access rate is of 48% of the hearing impaired population;
- by studying the survey data in Eurotrak (2015) which illustrates (for France) the course taken by hearing impaired persons until owning hearing aids ("the route to the hearing aid"): of 100% of hearing impaired people, 26% do not see their physician. Therefore 74% of people have a medical consultation related to hearing loss. In this population, 36% do not receive advice about hearing aid equipment. Thus, only 48% of people receive guidance about hearing aids. After renunciation of hearing aids, 34% of these people get hearing aids.

The expert assessments and the empirical analysis of access to hearing aids are sufficiently robust to maintain the reference target for people eligible to hearing aids of 50% of the hearing impaired population.

By revisiting the chronological data of surveys which estimate the access rate to hearing aids, by taking into account the rate of hearing loss prevalence, then by introducing the population INSEE data and considering for each year that 50% of the hearing impaired people should be equipped (target), it is possible to directly estimate the people being equipped and the people (who are not owners) able to be equipped per year (table 18). This estimation allows us to observe a noteworthy growth in the equipment rate, despite the differences in data depending on sources.

Table 18 – Estimation of the population being equipped in function of the sources – 2008-2015

Year	Survey and HL criteria	Population in metropolitan France	Access rate	Prevalence rate	Hearing impaired population	Equipment rate	Hearing aid owners / target	Eligible population for hearing aids	Hearing aid owners	Remaining eligible population for HAs (not owners)
2008	Handicap Santé (disabling hearing loss)	62 300 288	15.8%	11.2%	6 977 632	1.8%	31.6%	3 488 816	1 121 405	2 367 411
2008	Handicap santé (moderate to total AFL)	62 300 288	20.4%	8.6%	5 357 825	1.8%	40.8%	2 678 912	1 092 996	1 585 916
2008	ESPS	62 300 288	23%	10%	6 230 029	2.3%	46%	3 115 014	1 432 907	1 682 108
2009	Eurotrak	62 615 472	29.8%	10.4%	6 512 009	3.1%	59.6%	3 256 005	1 940 579	1 315 426
2009	Alcimed-DSS	62 615 472	31.7%	10%	6 261 547	3.2%	63.4%	3 130 774	1 984 910	1 145 863
2010	ESPS	62 917 790	23%	10%	6 291 779	2.3%	46%	3 145 890	1 447 109	1 698 780
2012	Eurotrak	63 536 918	30.4%	9.4%	5 972 470	2.9%	60.8%	2 986 235	1 815 631	1 170 604
2012	ESPS	63 536 918	37%	10%	6 353 692	3.7%	74%	3 176 846	2 350 866	825 980
2015	Eurotrak	64 395 242	34.1%	9.3%	5 988 758	3.2%	68.2%	2 994 379	2 042 166	952 212

Source: Authors, on basis on Alcimed-DSS data (2011), others available survey data and INSEE.

All data converge at this time towards a current size of one million people able to be equipped (and not already owning a hearing aid) in France.

This case-by-case review is beneficial in order to put the estimations of grey literature into perspective, since these estimations become quickly dated given the rapid development of hearing aid access (these estimations often rely on the study of the DREES (2014) for the year 2008). As an example, these estimations can be found in the literature:

- according to the CESE (2015), only 20% of hearing impaired people were equipped because of care renunciation for affordability reasons;
- according to IGAS (2014), the equipment rate ranges between 33% and 40% : 1.5 to 2 million people remain eligible for hearing aids (and do not own them) for every one million people who are already equipped[49] ;
- according to the Competition Authority (Autorité de la concurrence, 2016), there are currently 1.5 million equipped people for 4.4 million people eligible, all inclusive (thus an equipment rate of 32%);
- according to the survey 'UFC-Que Choisir' (2015)[50], there are 1.5 million people equipped for an eligible population not owning aids of 2 million people in 2012.

These estimations seem to be very approximate: either the number of people being equipped is incorrectly assessed, or the number of eligible people is wrong, or confusion persists as to the equivalence between the rate of hearing loss prevalence and the rate of people able to be equipped. Whatever the answer, access to hearing aids has grown significantly in a very few years whereas the number of people able to be equipped has hardly increased, despite the effects of demographic growth and ageing.

---

[49] According to the IGAS, France is characterised by an atypical situation, with a regulation failure which has led to high prices and low sales volumes. It considers that, for a similar expenditure, the reverse situation is found in English Health authorities: there is a high rate of reimbursement of demands and control of prices and products. The IGAS advise preferentially the reinforcement of the National Health Insurance's role in the running of the system and the financing policy for technical support equipment and the reinforcement of the HAS and CEPS' roles in the field of the technical support equipment assessment.

[50] The survey by UFC- Que choisir first considers the demand not being equipped on the basis of data for countries where the demand is totally reimbursed (Denmark, United Kingdom, Sweden). It then computes, for a population aged over 65, the number of devices sold in 2014 and deduces an average for 1,000 older inhabitants. This average value is the reference value from which a comparison in access is drawn for the same population in France. As this access is 2.41 times less, the authors estimate that for the past five years the sales not realised of devices on the basis of sold devices, and then deduce the number of people not being equipped, with an assumption of a binaural equipment rate of 80%. This estimation would better have taken into account several additional factors in order to be more reliable: the number of new buyers of HAs on the market each year (48% in DK, 54% in UK, 68% in France - data Eurotrak 2012); the median lifespan (4 years in DK against 5 to 6 years in France); the different rate of binaural equipment (84% in DK; 64% in UK; 74% in France). Therefore, this estimation for 2014 – whereas all studies show an increase in access since 2008 – is frail in terms of methodology. For example, if the same reasoning is applied to the same data for France and DK, but includes the new buyers on the market - 142.2*48% in DK and 51.5*68% - a ratio of 2 is obtained (and not 2.41), then keeping the Danish data for equipment lifespan (4 years) and the rate of binaural equipment (80%), the estimation of people not being equipped is about 1.2 million. Moreover, as shown previously, the rate of access for people aged over 65 years has been slightly slower than this rate for the whole population in France, which also introduces another bias to the results. Given that the initial estimation relies on overall sales in France to customers of all ages, it would have been better to base the reasoning on the whole adult population.

In any case, healthcare renunciation – given the lack of complementary health insurance or insufficient protection - is likely to concern people with low incomes who may forgo hearing aid care because of impossible costs or large out-of-pocket payments[51]. Moreover, if hearing aid renunciation is often understood as a result of financial constraints, we should also consider the role of psychological barriers, lack of information or the varying effectiveness of devices particularly among the elderly (cf. infra 2.3).

1.2.3 The hearing aid: a durable good associated with a paramedical service

The hearing aid is '*a hearing loss corrective electronic device*' in which adjustment of output depends on the frequency, in order to compensate for hearing loss: there are either "behind-the-ear" hearing aids which account for 88% of devices (classical behind-the-ear /children and elderly; micro-sound-tube and soft plastic ear tip / slight to profound losses; or remote earphones / slight to profound losses), or "in the canal" (completely in the canal, in the canal or in the ear/ moderate loss). They are digital devices in nearly 100% of cases (SNITEM, 2014).

The purchase of a hearing aid is characterised by a simultaneous purchase of the apparatus itself and long term delivery of a back-up service (on average 5 years), which makes audiologists different amongst healthcare suppliers. This role of delivery with the support of the network connecting the six manufacturers with central purchasing agencies, and the latter with audiologists[52]. Audiologists are either salaried or self-employed, depending on their type of practice, and might be employed by specialised groups in a retail chain (in a branch office or as a managing director) or they might operate independently, or as a member of a mutual distribution network[53].

The role of the audiologist is defined by the Public Health Code ("*Code de la santé publique*", CSP) and the Social Security Code ("*Code de la sécurité sociale*") and, since 2015, a *numerus clausus* restricts access to this profession[54]. In 2015, there are 3,064 salaried or independent professionals (table 19). The average annual growth rate of the professional demography (+5.3% for the period 1999-2015) is close to what was observed for hearing aid sales (+6.2%).

---

[51] The HCAAM (2013) considers that the stakes are to determine a good choice of complementary health care through better health risk management (fair and responsible contracts), since complementary health insurances are the main source of subsidies, and above all to question their ability to bring under control device sales prices; it supports the development of networks. In so doing, it excludes the possibility of the recapture of the hearing aid sector by the AMO and the adoption of applicable tariffs, because of the background of shortfall. Several scenarios are designed by the HCAAM, either a takeover of reimbursement by the AMO (by returning to a coinsurance rate for the reference tariff of 65% instead of 60%), or completely transfer to the AMC the whole reimbursement charge. At the time of this report, no additional clause has been in negotiation between the UNOCAM and the sector representatives.

[52] Such vertical integration has been permitted by the Competition Authority in December 2015 for the Audika group which is controlled by William Demant. Moreover, the purchasing agencies - contrary to wholesalers' distributors in the case of drugs – play a referencing, rather than a distribution role.

[53] Discount price being around 15% on the HAs prices (agreement of partnership quality-price). Cf. IGAS (2013).

[54] Decree of 15 July 2015. The *numerus clausus* has been fixed at 199 students in 2015-2016.

Table 19 – Evolution of the number and the density of audiologists in metropolitan France

Metropolitan France	Audiologists - ADELI Repertoire (salaried and independent) *Numbers*	Audiologists - ADELI Repertoire (salaried and independent) *Density for 100 000 inhabitants*
1999	1229	2,10
2000	1313	2,23
2001	1422	2,40
2002	1526	2,56
2003	1620	2,70
2004	1714	2,83
2005	1806	2,96
2006	1905	3,10
2007	2029	3,28
2008	2116	3,41
2009	2229	3,57
2010	2352	3,75
2011	2437	3,86
2012	2599	4,10
2013	2740	4,30
AAGR	**5,9%**	**5,3%**

Source: Biennial survey ESPS, data Eco-Santé OCDE and DREES (open data) (Available in February 2016).

Once the hearing loss diagnosed by the physician leads to medical advice for hearing aids, the audiologist plays an advisory role, delivering the device and the associated services[55]. This role, regulated by article L4361-1 of the CSP, is to ensure counselling of customers, the delivery and the adaptation of hearing aids, and follow-ups during the lifetime of the device, in a high performance technical facility. The main sequences that have to be followed are:

- The preliminary consultation, which leads to a standardised estimate, clearly differentiating on the one hand the prices of goods (apparatus) and, on the other hand, the prices of associated services[56] ;
- The adaptation consultation, in order to understand the device and its use in real-life situations, including a probationary period of 15 days;
- The adjustment consultations (1 to 3) dedicated to fine tuning and counselling;
- The follow-up consultations (twice a year) dedicated to maintenance and later adjustments.

The price of a hearing aid comprises therefore the cost of the device and the long-term follow-up, including the apparatus, the audiologist's time, the technician's or assistant's salaries (administration) and the technical facilities. The estimated time devoted to the user is variable in the literature:

- it ranges between 11.5 hours to 20 hours according to the CNC (2000);

[55] The freedom of counselling leads to a possible information asymmetry between the patient and the audiologist, with the audiologist being incentivised to make more frequent references to upmarket products because of a higher profit margin.

[56] This clarification is imposed by the « Macron » law of 6 August 2015. The costing presents the pre-tax sale price and the service price, the net price including VAT and the reference tariff fixed by the LPPR (article L. 165-1 of the social security Code, title 2.

- 10 hours according to the Court of Accounts (Cour des comptes, 2013);
- 12 hours to 15 hours over 5 years, including 4 hours for initial adaptation according o IGAS (2014)[57] ;
- 10 to 12 hours according to Alcimed-DSS (2011). The report points out that the combination of high manufacturers' sales prices and the human time required for a high quality fitting limits the possibility of cheaper supplies (no "discount" equipment).

Contrary to some medical devices which only require a short amount of time for counselling, using hearing aids calls for deeper acquaintance and "cognitive" adaptation, depending on the capabilities of the auditive nervous system, where the stakes are compliance, and thus, improvement in the quality of life that may not be perceived immediately. This adaptation is, according to the report Alcimed-DSS (2011), '*a key phase for a successful equipment*', and requires a long-term follow-up and a confident, sharing relationship between the patient and the audiologist. The report also underlines given that "*the psychological stake is strong and the population of patients mostly older, it is not rare that adaptation sessions also play a social role*"[58].

This point of view is taken up by the CESE (2015) for the whole set of medical devices, which qualifies them as "*user-dependent*" products to the extent that therapeutic results depend on patient compliance with recommendations and that specific patient counselling is required. The IGAS (2014) also underlines the difficulty for assessing the cost of the service, which is a decisive factor in satisfaction (and thus of patients' compliance). All this differentiates this technical support equipment from others, since the device is not separable from counselling and tune-up on a long-term basis, and where the purchase cost does not divide device and service delivery.

1.2.4 Hearing aid pricing issues: an analytical economic framework

In the framework of hearing aid delivery mentioned above, is it reliable to dissociate the apparatus and the service for pricing? This issue, which is regularly questioned in the grey literature, would require an assessment of the added-value for the combination of apparatus-service:

- Arguments in favour of this decoupling suggest that pre-payment – or prospective payment – does not ensure the effective fulfilment of the service (in case of patient decease, centre closure etc.[59]) or any quality improvement in the follow-up (as there is no incentive to make an effort for the service provider);
- Arguments against this decoupling put forward, over all, therapeutic efficiency, which is linked to compliance and patient satisfaction, which themselves depend on the counselling during the healthcare pathway.

[57] Based on UNSAF declarations, cf. addendum 5 p. 19.
[58] p. 42.
[59] Patient decease should not lead to a charge for the provider, given that this rule doesn't apply in the whole financing situations of providers, whatever it is (physician, dentist…). The cases of a centre closure or retiring provider, even though quite marginal, should lead to a transfer rule of patients between providers, which could be implemented by the design of a clearing house.

These two classes of arguments rely on fundamentally different assumptions: in the first case, it is implicitly assumed that healthcare demand does not depend on the quality of the follow-up (no reputation effect, no long-lasting provider-patient relationship, no competition between providers, providers not being altruistic). In the second case, it is implicitly assumed that healthcare demand does depend on the quality of follow-up (reputation effects, durability of the provider-patient relationship, competition in quality between providers, altruistic providers).

This question of decoupling the prices of "apparatus-service" refers to a classic issue in "moral risk" situations, where incentive based reasoning is required in a framework with information asymmetry between the purchaser and the provider[60].

The analytical framework:

- The financing body (health care insurance) designs payment rules in order to compensate the provider (the audiologist), expecting to pay the least for the best quality;
- The financing body, which cannot consistently control provider activity, is facing an information asymmetry that implies both efforts to achieve cost reduction and efforts to improve quality;
- It has to design a payment rule likely to incite the provider to choose the best 'cost-quality 'pairing, namely the "optimal cost" and the "optimal quality";
- It has to choose between 3 pricing rules (or even a combination of the 3):
    - A global budget *for all patients*: this includes the cost of the devices in order to satisfy the demand, and the provider's salary which doesn't depend on demand size. This is the *prospective* payment system of the United Kingdom or in Scandinavian countries (the expenditure is forecast *ex ante*);
    - A fee-for-service applied both to piecework done (sold devices) and services (depending on the provider's counselling activity). This is the decoupled system, which is *retrospective* (payment depending on sold devices and effective consultations);
    - An overall payment by *case/patient*, being a pricing both for apparatus and service. This is the prospective payment for the combination apparatus-service in France, Germany or Switzerland.

- These three payment rules do not present the same properties in terms of cost/quality incentives:
    - The global budget allows expenditure control and forecast. However, since the provider's payment is not dependent on quantity and quality of care, cost and quality incentives are lacking. Therefore, he/she reduces his/her effort to the minimum level, translating to a demand rationing (delays in equipment and moreover follow-up delays). In such a system, in general patients have a reduced choice of provider (and thus, cannot make use of their sensibility to quality in order to stimulate the provider) but they are totally subsidised. Their demand is high because of total refunding and the activity of providers is driven by the equipment more than by the follow-up. The consequence is a certain

[60] Cf. for exemple Dranove and Satterthwaite (2000) or Mougeot and Naegelen (2011).

non-observance/non-compliance (devices owned but not worn) and finally, costs are higher because of the lower level of service quality (ratio salaries/effective activity);

- The fee-for-service payment presents an opposite set of incentives. It creates the incentive to multiply consultations and to sell piecework. In this situation, the audiologist is incentivised to sell a great number of devices and a great number of counselling and follow-up consultations. The audiologist's degree of freedom depends on the nature of demand, regardless of the quality of care, and on the insurance coverage rules for the package:

    - *If patient demand is independent of quality of care:*

        - If demand doesn't depend on the perceived quality of care (for example, a totally passive and manoeuvrable demand), and if healthcare insurance coverage is high, the provider will saturate its activity by choosing the more profitable route: high sales of devices associated with little follow-up, or sales of useless services (induced demand). The system is costly for society;
        - If healthcare insurance coverage is low, people who are willing to pay will be equipped and will be frequently offered either new devices, or a great number of services, whereas people who are not able to pay will renounce care (at least for follow-up services, even for devices). The level of quality will be optimal for the people who are willing to pay, but this system is likely to be costly and is unfair;

    - *If patients' demand depends on quality of care:*

        - If patients are sensible to care quality (for example, well-informed patients), the provider cannot manipulate them because he runs the risk of losing his patients, but he will still have an incentive to multiply follow-up services if healthcare insurance coverage is high (patient-provider coalition): the level of quality is optimal but the social cost is high;

        - If patient demand is sensible to quality but healthcare insurance coverage is low, then the renunciation of care will remain, and thus the equipment failure is likely to be higher (some of the patients will renounce follow-up services, even for equipment). The level of quality isn't optimal because of the possible renunciation of care (or possible non-compliance in case of access to equipment) whereas the cost of follow-up for the others may be high.

- The overall payment by case/patient looks like the actual payment for hospitals in France: it combines the act and service in an indivisible way (for example,

hip replacement or cataract). This system presents the optimal incentives under some conditions and is generally more desirable than the other payment systems (this is why public authorities have given up the global budget system for public hospitals and the fee-for-service system for for-profit hospitals). However, this system isn't ideal and is not defect free. There are also two cases to be considered, depending on the nature of demand:

- *If patient demand is independent of quality of care:*
  - If patient demand does not depend on the quality of care (passive and manoeuvrable). In this case, the provider will have the incentive to propose the most profitable device and to reduce the services that are associated with it. Efforts is reduced to the minimum level, with possible equipment failure. If healthcare insurance coverage is high, the provider will saturate the demand in order to bill the greatest number of devices with the least possible follow-up services;
  - If healthcare insurance coverage is low, the provider will have an incentive to capture patients who are willing to pay by offering different devices at different prices in order to increase revenue, while reducing its quality effort to the minimum level in terms of follow-up services. If the competition between providers is poor, it will be easier for the provider to capture the clientele. This is the argument of critics of the actual coupling apparatus-service in France;

- *If patient demand depends on quality of care:*

  - If patient demand depends on the quality of care (they are interested in the perceived quality of apparatus and service, and are likely to renew purchases over time). In this case, the provider will have an incentive to propose an attractive combination of device and service, namely the best quality for both dimensions at a profitable cost for him. If healthcare insurance coverage is high, the provider will have an incentive not to multiply the follow-up consultations that would reduce margins, but he will have an incentive to offer enough services in order to keep his clientele, sensible to quality. He will have also an incentive to propose the most profitable devices and to replace them quickly in time because of the large reimbursement (coalition patient-provider), thus an optimal situation in terms of quality and compliance but not in terms of social costs. In such a case, healthcare insurance would be well advised to set a minimum delay for device renewal as a first condition for reimbursement (for example, 5 years) and a ceiling sale price as a second condition for reimbursement;

- If healthcare insurance coverage is low, the provider will have a strong incentive to deliver the optimal quality in order to retain customers, whatever the type of purchased product (they will try to drive choice towards the more profitable upmarket products), but the issue of renunciation of care will remain. Particular attention has to be paid to the possible strategy of dumping and cream-skimming, which would introduce bias to this scheme (choice of less severe patients as better from the follow-up perspective, withdrawal of care for certain severe patients, different levels of quality depending on the ability or willingness to pay). In this case, the provider must be required satisfy demand, whatsoever it be and to impose at least a minimal follow-up service for each of client.

In summary, the issue of coupling or decoupling hearing aid devices and services is not as mundane as it would appear. One of the difficulties encountered by the actual prospective 'payment by case' relies on the specific role of the audiologist, being the prescriber of the device and, thus, the prescriber of the price of the device-service pair. To put it simply, let's suppose that, in France, demand for hearing aids is relatively aware of the quality of care. This assumption is the more reliable for 3 reasons: 1) the out-of-pocket sum is so high that it induces patients to be aware of the expense and to search for information in order to realise a trade-off; 2) of the oldest patients, the relationship between the provider and the patient is likely to be long-lasting. In a context of competition, quality and reputation are likely to play a noteworthy role in holding a satisfying relationship for the user, for a "experience service" whose quality is only known after the purchase (and where the follow-up is one of the judgement criteria)[61] ; 3) a positive reputation effect derived from the counselling and the follow-up allows the provider to increase his own demand.

The different provider's behaviours in the three cases of payment systems, under the assumption of total refunding of patients' demand (an alternative scenario in comparison to the current situation in France), would be characterised as follows:

- Providers paid on the basis of a global budget or salaries will reduce their activity and quality effort and, as long as their own activity doesn't depend on perceived quality by the patient, the effort is set at the minimum level, but the expenditure for equipment is controlled. This system is not conceivable in France since it would imply for healthcare insurance a free delivery of devices and a wage system for audiologists;

- Providers paid on the basis of piecework and consultation fees will increase their efforts in quantity and quality, but this system would be costly for healthcare insurance;

[61] In economics, an experience good or service is a good or service whose quality is only known after the purchase. A confidence good or service is a good/service whose quality is never known by the purchaser. A search good or service is a good/service whose quality is known before the purchase. On this topic of information searching by the patient, it should be noted that the IGAS (2014) considers that: "attempts by the person before the technical support equipment purchase is in itself non- compulsory. However, such an obligation would be particularly reliable for technical support equipment requiring strong personalisation and/or a high cost (hearing aids constitute a good example of these)". p. 76.

- The prospective payment by case/patient offers the advantage of providing better incentives for cost reduction (not multiplying consultations) and in quality improvement (patient satisfaction and reactivity). Moreover, it covers the provider under the risk of a distribution of heterogeneous cases (severity), costly cases being compensated by non-costly ones (as in the hospital pricing case), under the condition that the provider does not select the patients (withdrawal from severe cases) or does not discriminate against them (by differentiating the levels of quality). The health insurance expenditure is controlled under the condition of determining a ceiling-price for sales and a minimum delay of use.

What are the options for National Health Insurance in the case of a prospective payment per case and a total reimbursement?

- Option 1 – To cover the total price of the equipment by fixing a ceiling fee depending on the range: in this case, all the prices will be bounded by the maximum price of the best range, and so the system would be costly with an optimal quality and a total coverage of needs;
- Option 2 – To cover the total price of the equipment by fixing a bottom price corresponding to the downmarket or middle market price, by letting the purchaser choose the devices and pay the costs out of his own pocket: the cost is controlled, the quality is optimal, and with a coverage of needs (this system is similar to the fee reference tariff applied to drugs);
- Option 3 – To organise the market into networks of contracted providers: this gives the best control of tariffs but also a risk of equalisation between a drop in the product price and an implicit increase in quality price (i.e. a reduction of follow-up quality that would result from the patient's status who is captive because of his insurance contract, except if the insurance companies made the provider-networks compete each year on the basis of patient satisfaction, that is according to a quality/price ratio, in order to conclude agreements). This option is conceivable but is costly in terms of information searching and regulation.

Starting from an efficiency point of view, and assuming that the issue of equity is solved by social subsidising of equipment, option 2 appears to be more desirable, or a combination of options 2 and 3.

International comparisons show that in general the goods and the service are indivisible, but that compliance and patients satisfaction are quite variable, depending on financing rules, the range of prostheses and the follow-up service (which is related to access rules and payment rules in the health system). As will be shown, this comparative analysis for people being equipped with hearing aids seems to demonstrate the existence of a link between, on the one hand, compliance/patients' satisfaction and, on the other hand, hearing aid financing schemes and types of audiologist follow-up.

1.3 Hearing loss prevalence, hearing aid access and pricing in comparable countries to France

The aim of this section is to complete the previous overview with some key references and for several comparable countries. The access rate is hearing aids is studied in particular, on the basis of cross-referenced data relating to the observed access rate, the compliance rate and the real rate of eligibility for hearing aids.

1.3.1 Hearing loss prevalence, equipment rate and access rate to hearing aids

International comparisons rely on Eurotrak data (EHIMA, 2015) gathered from panel surveys (table 19). In France, it should be underlined that the estimated prevalence rate of hearing loss is very close to the previous data: Eurotrak survey assess it to be at 10.4% in 2009 (whereas the DREES estimation in 2008 ranged between 11.2% as for 'disabling hearing loss' and 8.6% as for moderate to total AFL. In contrast, the rate of hearing aid owners was higher in 2009 (3.1%) compared to the DREES estimation (1.8% in 2008) and lower in 2012 (2.8%) compared to the ESPS survey (3,7%). The access rate to hearing aids is estimated to be 34.1% in 2015 (cf. supra regarding the variability of estimations).

Hearing loss prevalence rate across the compared countries is very similar, ranging from 8% (Switzerland) to 12.1% (Germany).

Table 20 – Estimations for hearing loss prevalence rate, equipment rate, and access rate to hearing aids – Eurotrak triennial surveys (2009, 2012, 2015)

Eurotrack Surveys	HL prevalence rate (in % of total population)			Equipment rate (in% of total population)			Access rate for HAs (in % o hearing impaired people)			% Binaural equipment
Country/Year	2009	2012	2015	2009	2012	2015	2009	2012	2015	last year availabl
France	10.4	9.4	9.3	3.1	2.8	3.2	29.8	30.4	34.1	70
United Kingdom	9.5	9.1	9.7	3.7	3.7	4.1	38.6	41.1	42.4	61
Switzerland	nd	8.8	8	nd	3.4	3	nd	38.8	41.4	72
Italy	nd	11.6	11.7	nd	2.9	3	nd	24.6	25.2	57
Japan	nd	10.9	11.3	nd	1.5	1.5	nd	14.1	13.5	46
Germany	13.1	12.5	12.1	4.2	4.2	4.2	31.8	34	34.9	75
Denmark	**nd**	**10**	**nd**	**nd**	**4.8**	**nd**	**nd**	**47.8**	**nd**	**82**
USA	11.3	nd	nd	nd	nd	nd	24.6	nd	nd	nd
Norway	nd	8.8	nd	nd	3.7	nd	nd	42.5	nd	74

Source: Authors on basis of EHIMA data, 2015

However, the hearing aid equipment rate varies by a factor of 1 to 3, Japan being the least well equipped country (1.5%) and Denmark the best. This variation is also found in the hearing aid access rate for hearing impaired people, it is particularly low in Japan (13.5%), quite weak in Italy and the USA (around 25%), mid-point in France and Germany (about 34%) and high in the United Kingdom, Switzerland and especially in Denmark (47.8%). Thus, Denmark will be used in this study as the reference value target, even if this is only based on one year's data (2012). Moreover, the share for binaural equipment is high as the access rate is high.

The analysis of Godinho (2016) compares observed sales in nine European countries, gathered in 2011 from the European market, with the demographic data[62]. He identifies 3 groups of countries:

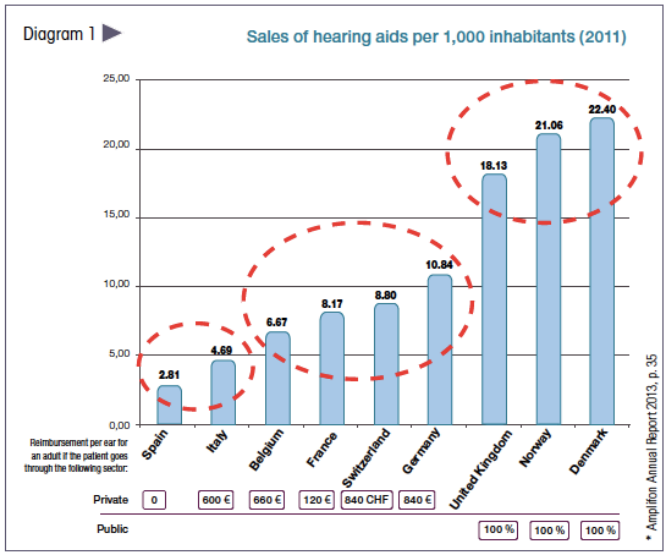
- Those where the equipment rate is lower than 5/1000 inhabitants (Italy, Spain). The OOP does not suffice to explain the poor access level, cultural factors alsoto play a part;
- Those where the equipment rate ranges between 5 and 11/1000 inhabitants: Belgium, France, Switzerland, Germany. The coverage for hearing aids is quite similar in these countries (if we consider the additional role of complementary health insurances which is not included in the French financing reference chart). It should be noted that these health systems are predominantly Bismarck organisations (i.e. Social Insurance) except in Switzerland (regulated liberal organisation);
- Those where the equipment rate ranges between 18 and 23/1000 inhabitants (United Kingdom, Norway, Denmark), namely countries under National Health Systems with a total or nearly total refunding for hearing aids.

Figure 1 – Sales of hearing aids for 1,000 inhabitants in 2011

Table 1

	Population (2012)*	Devices sold (2011)**	Devices sold/ 1,000 inhabitants (2011)
Spain	46 196 276	130 000	2.81
Italy	60 820 696	285 000	4.69
Belgium	11 094 850	74 000	6,67
France	63 409 191	518 000	8.17
Switzerland	7 954 662	70 000	8.80
German	81 843 743	887 000	10.84
United Kingdom	62 989 551	1 142 000	18.13
Norway	4 985 870	105 000	21.06
Denmark	5 580 516	125 000	22.40

*Eurostat Population 2012. Data extracted by Richard Darbéra, Patient contributions for hearing aids, 20/11/2014
**_Audio Infos_ No 173: The market in Western Europe: 2011 vs 2010, July - August 2012, p. 22
**_Audio Infos_: 1,221,602 hearing aids sold in 2012 in the United Kingdom, up 7% from 1,142,000 in 2011, 08/03/2013
**In Switzerland, change in reimbursement mid-2011: 70,000 in 2010, 90,000 in 2011, 50,000 in 2012. Choice of mean volume 2011-2012, equal to that of 2010.
** Belgian National Accounts Institute, "Étude sur les prix, les marges et le fonctionnement du marché des appareils auditifs en Belgique", décembre 2014, p.59
** In the UK, as the detail of the number of new devices actually delivered by the NHS and those for repairs is not specified in the studies mentioned above, we will base our calculations on the overall quantity.



Source : Godinho, 2015/2016

These strong differences ask for an in-depth study of hearing aid access.

[62] The market analysis relies on a survey which is available online (Grant-Salmon, 2013) and demographic data are extracted from the European database Eurostat.

1.3.2 Estimation of the *real* access rate for hearing aids depending on the eligible population and on compliance

Starting from the former previous data (section 1.1 and 1.2), from the Eurotrak survey data and using the same assessment methodology as Alcimed-CNSA (2009), it is possible to propose an estimation for the real access rate depending on the eligible population and on compliance in the compared countries.

The Alcimed-CNSA methodology is as following: given the existing different definitions of hearing loss in European countries, the study applies a uniform rate of hearing impairment of 12%, in order to deduce the eligible population (the rate of 50% of the hearing impaired population is the consensual reference according to experts) and, then, to estimate the rate of hearing aid owners (here, "effective access rate"). In the Alcimed-CNSA study, two methods are compared, taking (or not) into account the real rate of users (excluding the number of people owning hearing aids but not wearing them)[63]. In our study, we combine both these previous methods used by the Alcimed-CNSA in order to realise an estimation of the equipped population, who wear their hearing aids (more than one hour a day), as these data are available in the Eurotrak survey 2015 (cf. tables 21 and 22). However, we do not normalise the prevalence rate at 12%, but we retain the observed prevalence rate in each country in order to better integrate the national definitions of hearing loss and hearing aid eligibility. These estimations are presented in table 21.

Table 21 – Estimation of the *effective* access rate

Estimated rates	Compliance rate	Rate of not worn hearing aids (less than one hour a day)	Eligible population for hearing aids	Effective access rate (access rate rate/50% of HL prevalence rate)			Real access rate related to compliance rate		
Country	Last available year	Last available year	Uniform rate (experts consensus - Alcimed-CNSA 2009)	2009	2012	2015	2009	2012	2015
France	90%	10%	50%	60%	61%	68%	54%	55%	61%
United-Kingdom	81%	19%	50%	77%	82%	85%	63%	67%	69%
Switzerland	88%	12%	50%	nd	78%	83%	nd	68%	73%
Italy	90%	10%	50%	nd	49%	50%	nd	44%	45%
Japan	77%	23%	50%	nd	28%	27%	nd	22%	21%
Germany	90%*	10%*	50%	64%	68%	70%	57%	61%	63%
Denmark	80%	20%	50%	nd	96%	nd	nd	76%	nd
Norway	76%	24%	50%	nd	85%	nd	nd	65%	nd

* In Germany, the compliance rate (not available) is estimated on the basis of its main survey (2015) and is normalised at the same level as for France, given similar data and given the compliance rate in 2009 (15% of the equipped population).

Source: Authors on basis of EHIMA data, 2015

Results of this estimation which should be noted:

- Effective access rates that are notably high in United Kingdom (85%), Denmark (85%) and Norway (85%) approach the total coverage of needs, which can be explained by free access (or almost free access in Sweden) for downmarket or middle-market hearing aids, where prices are slightly lower than those in France;

[63] Estimated equipment rates (out of compliance) were: 69% in Sweden, 84% in the United Kingdom, 50% in Germany, 16% in Spain, 27% in Italy. The study underlines that these rates don't take into account compliance whereas a rate of 45% is observed in the United-Kingdom among owners who do not wear their hearing aids.

- The effective access rate in France rises to 68%: it means that 2/3 of the eligible population is equipped, and thus the remaining number of people who should have access to hearing aids is around 1 million (based on previous estimations), a mid-rate level which can be explained by the financial barrier;

- Nevertheless, the compliance rate (estimated as the rate of people wearing their hearing aids more than an hour a day) is second-rate in the 3 countries associated with a high effective access rate (compliance / UK: 80%, DK: 81% and NW: 76%), hence the real access rates are obviously lower: 69%, 76% and 65%. These countries lose 15% to 20% of hearing aid owners in the estimated real access rate because of this quasi-renouncement of equipment wear;

- At the same time, the compliance rate is particularly high in France (90%), Switzerland (88%) and Germany (90%). These high rates have less impact on the real access rate in comparison to the previous countries;

- As a consequence, real access rates tend to converge, but for different reasons: on the one hand, higher access – because free access - but associated with lower compliance, on the other hand, lower access – because costly access – but associated with higher compliance. These rates range between 61% to 76% of equipped and compliant patients, France has the worst score (apart from peculiar cases such as Japan and Italy).

- If France had Denmark's effective access rate (96%), its real access rate would be 86%, which would give it the best observable rate of all the countries thanks to compliance;

- Only Switzerland combines a high access rate and a satisfactory compliance rate;

- As for Japan, it combines a low access rate and a poor compliance rate[64], whereas Italy combines a middling access rate with a very satisfactory compliance rate.

Taken thus, France presents a real rate of use close to 61% (combining the rate of *eligible people for hearing aids* and the rate of *effective* use), a rate similar to those of the United Kingdom, Germany and Norway and starting from very different situations in terms of financial access to equipment.
If there is room for improvement in France regarding the need for hearing aid equipment – due to financial impediment - there is also room for growth in countries where hearing aids are (almost) freely delivered but where the compliance is insufficiently performant. A review

[64] This could be explained by a combination of device quality (downmarket products) and follow-up quality (often poor): indeed, one third of purchases were made by mail ordered in opticians' shops (Eurotrak Japan, 2012). It must be noted that since the decree of 13 August 2014 (modifying the decree of 15 February 2002) fixing the goods that pharmacists are allowed to dispense; they are entitled to sell "assistants for hearing" pre-set at a maximum power of 20 dB. This equipment is then sold freely in pharmacies *over-the-counter*, at a lower price of 500 euros (in general 300 euros). They are useful for patients with a slight hearing loss and ought to be used occasionally according to the General Directory for competition, consumption and fraud repression ("*Direction générale de la concurrence, de la consommation et de la répression des fraudes*" (www.economie.gouv.fr - 8 March 2016).

of financial rules relating to hearing aids has to consider the compliance factors determining the effective use of equipment and, thus, the level of satisfaction for hearing aid users. A trade-off has to be undertaken between, on the one hand, financial access and, on the other hand, suppliers' and users' commitment to hearing aid use.

1.3.3 Determinants of access to hearing aids

The Eurotrak survey allows for a more precise analysis of the reasons leading to access or renouncement of hearing aids (table 22), based on qualitative statements. It should be noted that:

Table 22 – Analysis of the access factors – Triennial data Eurotrak (2009, 2012, 2015)

Country	Main factor of renouncement of hearing aids	Rate of people considering a financing failure	Rate of owners not wearers	Rejection feeling for owners	Factors leading to access	Coverage impact or price effect	People stating to access for HA < 1 year
France (2015)	Financial barrier, other priorities, ENT advice	30%	4% (0 hour) ; 10% (less than 1 hour a day)	No at 87 % (and contrary to the situation without HA)	HL degradation, ENT advice, audiologist advice	Reliable only for non equipped people	8%
United Kingdom (2015)	HL considered as not severe enough, discomfort, embarassment	21%	11% (0 hour) ; 19% (less than 1 hour a day)	No at 80 % (and contrary to the situation without HA)	HL degradation, GP advice, ENT advice, audiologist advice	Reliable only for non equipped people	13%
Switzerland (2015)	HL considered as not severe enough, no noisy environment	39% for lack of information on reimbursement rules, 15% for financial inaccessibility	2% (0 hour) ; 12% (less than 1 hour a day)	No at 95 % (and contrary to the situation without HA)	HL degradation, ENT advice, spouse advice	Reliable only for non equipped people	11%
Italy (2015)	HL considered as not severe enough, other priorities	24%	5% (0 hour) ; 10% (less than 1 hour a day)	No at 71 % (and contrary to the situation without HA)	HL degradation, ENT advice, children advice, audiologist advice	Reliable only for non equipped people	15%
Japan (2015)	Discomfort, insufficient compensation, HL considered as not severe enough	only 9% know the financing rules	7% (0 hour) ; 23% (less than 1 hour a day)	No at 68 % (and contrary to the situation without HA)	HL degradation, ENT advice, spouse/children advice, centre advice	Reliable only for non equipped people	6%
Germany (2009)	HL considered as not severe enough, inefficiency, discomfort	61% don't know the financing rules	4% (0 hour)	No at 89% (datum 2015)	HL degradation, ENT advice, audiologist advice, close's advice	Reliable only for non equipped people	19% (datum 2015)
Denmark (2012)	HL considered as not severe enough, discomfort	48% don't know the financing rules, 16% assume a low financing - the price is not a determining factor	13% (0 hour) ; 20% (less than 1 hour a day)	na	HL degradation, close's advice, free access	Free access	14%
Norway (2012)	No noisy environment, HL considered as not severe enough, discomfort	63% don't know the financing rules, 10% assume a low financing - the price is not a determining factor	10% (0 hour) ; 24% (less than 1 hour a day)	na	HL degradation, close's advice, ENT advice, audiologist advice	Low	10%

na : not available

- Source: Authors on basis of EHIMA data, 2015

- The financial barrier predominantly affects France (30% of people consider that hearing aids are poorly reimbursed, that is, the highest rate in European statements) while the main argument for non-access is the level of hearing loss (considered as slight), then the discomfort or even infrequent noisy situations;

- Factors leading to access are shared: hearing degradation, medical or paramedical advice, advice from close relatives. This last factor underlines the fact that it is above all a subjective assessment of hearing loss by people close to the persons suffering hearing loss which leads to access more than the self assessment by the person him/herself.

- Compliance (inversely proportional to the sum of people who never wear their hearing aids and people who wear them for less than an hour a day) varies strongly: it is quite low in Japan, the United Kingdom, Denmark and Norway where either the rate of equipment being given-up or only occasional used concerns 19% to 24% of equipped people. It is better in France, Italy and Switzerland (with a 10% to 11% attrition rate among equipped people);

- In Japan, the rejection feeling when wearing hearing aids is stronger than in other countries, even if this feeling appears to be less important for hearing aid wearers than for hearing impaired people without hearing aid equipment (isolation).

Eurotrak data 2012 relating to the effective access rate have given rise to further, complementary analysis by Godinho (2015b), who considers the following indicators:

1. The metropolitan population referenced in Eurostat (in 2012) ;
2. Devices sold in 2011;
3. Binaural equipment rate in 2012;
4. Hearing loss prevalence in 2012.

Thus, the number of people who purchased equipment in 2011 is estimated in each country on the basis of the number of sold devices related to the binaural equipment rate (= (sold devices number)/ (2*binaural equipment rate + 1*monaural equipment rate)). The rate of people having purchased an equipment (or buyer rate) in 2011 can be deduced (number of buyers/hearing impaired people number).

Figure 2 – Estimations of several access rates in the hearing aid market in 2011

Table 2 ▶

	Population (2012)	Devices sold (2011)**	Rate of bilateral fitting (2011-2012)*	Persons fitted (2011)	Persons fitted /1,000 inhabitants (2011)	Prevalence of hearing loss(2012)*	Persons fitted/100 hearing impaired
Italy	60 820 696	285 000	44%	197 917	3.25	11,6%	2.81
France	63 409 191	518 000	74%	297 701	4.69	9,4%	4.99
Germany	81 843 743	887 000	76%	503 977	6.16	12,5%	4.93
Switzerland	7 954 662	70 000	74%	40 230	5.06	8,8%	5.75
United Kingdom	62 989 551	1 142 000	64%	696 341	11.05	9,1%	12.15
Norway	4 985 870	105 000	76%	59 659	11.97	8,8%	13.60
Denmark	5 580 516	125 000	84%	67 935	12.17	10,0%	12.17

*Eurotrak 2012

** In the UK, overall quantity for sold and repaired devices.

Source: Godinho, 2015b

The author estimates the ratio between the observed access rate given by Eurotrak (number of users/number of hearing impaired people) to the buyer's rate, in order to deduce a compliance index.

Figure 3 – Estimation of an compliance index

Table 4 ▶

	% users / total hearing impaired(2012)*	Persons fitted / 100 hearing impaired	Compliance index
Italy	24.6	2.81	8.77
France	30.4	4.99	6.09
Germany	34.0	4.93	6.90
Switzerland	38.8	5.75	6.75
United Kingdom	41.1	12.15	3.38
Norway	42.5	13.60	3.13
Denmark	47.8	12.17	3.93

*Eurotrak 2012

Source: Godinho, 2015b

This compliance index is equal to the inverse of the new purchases rate for the whole population of hearing impaired people owning hearing aids. The implicit assumption of the author is the following: if, as in Denmark, 25% of hearing aids owners purchase new devices in 2011, and given the average lifespan of a device (5 years), the whole eligible population should be equipped, even including new buyers on the market. Yet, the hearing aid access estimated by Eurotrak shows that the latter is less then forecast regarding market device penetration. The author deduces that a portion of population renounces its equipment, and doesn't even state that it owns them (maybe after having been equipped and given up). The same reasoning applies in the United Kingdom where withdrawal would be high compared to the French compliance index. This reasoning brings into light another explanation of the compliance issue, since it considers that a rapid rotation rate of devices is a reliable indicator of compliance by including 'desertion': a high rate would result not only from a total refunding of hearing aids but also from significant desertion.

From our point of view, other factors might be behind this explanation: free provision encourages rapid replacement of hearing aids, especially if they are downmarket devices, users being willing to access a presumed better quality new devices; and even, free provision creates a demand for which hearing aids are not suited, an assumption to be investigated.

1.3.4 The role of health systems in hearing aid access and perceived efficiency by users

The price of a hearing aid on the western European market is very similar, but coverage in France is remarkably poor (table 23). The average price on the French market is slightly higher than in other countries, the average bottom of the range price is similar and the average top of the range price is lower, so there is a strengthening of sales prices between the 3 lines in regard to other countries.

Table 23 – Scale of price levels for a hearing aid in several European countries

Country	Sweden		United Kingdom		Italy		Germany		Spain		France	
Price inc. VAT	Euros/HA	OOP	Euros/HA	OOP	Euros/HA	OOP	Euros/HA	OOP	Euros/HA	OOP	Euros/HA	OOP
Basic	na	na	na	na	640	0%	400	0%	na	na	na	na
Downmarket	979	0%	570 to 1300	0%	700 to 800	0%	1100	0%	1100 to 1600	100%	950	87%
Middle market	979 to 1879	100%	1800 to 2300	100%	1000 to 2000	Price minus fee	1100 to 1300	Price minus fee	1700 to 2100	100%	1550	92%
Upmarket	2792	100%	2700 to 2800	100%	3900	3300	2400 to 2600	2000 to 2400	2200 to 3100	100%	1850	94%

na : not available

Source: Authors on basis of Alcimed-CNSA data (prices of 2009) and Competition Authority in France (price of 2014)

Countries that cover the total price of hearing aids or a fixed price in general offer bottom-of-the-market or midmarket devices. Apart from Spain, systems do not reimburse on age or disability criteria. Countries where audiologists' counselling is considered 'low' (United Kingdom) are characterised by reduced compliance : "45% of users benefiting from a NHS hearing aid do not wear it, because it is badly tuned or badly adjusted to their type of hearing loss"[65]. The out-of-pocket amount varies between countries according to two models : either the health system directly delivers the hearing aid and the owner cannot opt for a more expensive device, not included on the list of approved products (no OOP), or the health system pays a fixed price corresponding to bottom of the market devices (no OOP), the purchaser then choosing the market line on the basis of his willingness to pay any supplement beyond the basic fee (such a system based on willingness to pay is similar to 'reference price' or 'standard tariff of responsibility' systems). Patient satisfaction is higher in the case of possible choice, while the others are able to opt out towards the private market as in the United Kingdom.

In 1999, although the average French price for a hearing aid was the lowest among the comparable countries, hearing aid access was also one of the lowest of developed countries (by a factor of 2 to 4 times). France, along with Italy; appeared amongst countries where social financing was lowest, reimbursing only one ear (partial reimbursement), while only Spain provided no coverage.

[65] Alcimed-CNSA (2009), p. 10.

Table 24 – Comparison of the price and reimbursement rules for a digital hearing aid in several comparable countries in 1999 (in francs)

Countries	Price for a hearing aid in francs	Reimbursement rules
Netherland	11 390	Social security : 3 800 F (2 ears)
Switzerland	13 500	75 % for retired people, 100 % for working people (2 ears)
USA	21 000	Private insurances
Germany	11 200	80 % (2 oreilles).
Spain	12 400	No reimbursement
Italy	12 400	670 F (1 ear).
France	9 000 to 10 000	1 310 F (1 ear

Source: Conseil national de la consommation, 2000

The price level, the degree of coverage and/or the market line of devices could have an impact on its median lifespan, although this only appears as a trend and is not systematically observable (table 25). In France, the median lifespan is 6 years, whereas in the United-Kingdom and Denmark it is 4 years. For actual hearing aid users, the daily time of use is 8 to 9 hours. It should be noted that this daily time in Denmark is in contrast to the given-up or occasional rate (20%): the distribution analysis of the time of use in hours shows that 2 types of population are concentrated at the extremes, the non-compliant users and the very compliant users (cf. Eurotrak DK, 2012, p. 56).

Table 25 – Comparison of indicators of equipment lifespan and on daily length of use

Indicators	Median lifespan of a HA	Average age of equipment (at tl time of the survey)	Daily length of use in hours
Country	Last year available	Last year available	Last year available
France	6	2.9	8.6
United Kingdom	4	2.1	8.1
Switzerland	6	2.1	9,0
Italy	4	2.5	8.4
Japan	5	4.1	6.8
Germany	5	na	na
Denmark	4	4.1	9.2
Norway	6	2.7	7.9

na : not available

Source: Authors on basis of EHIMA data, 2015

As regards overall satisfaction, the survey shows that France has the best rates with 84% satisfied users (comparable rates with Switzerland). These rates are clearly better than those of Germany, the United Kingdom, Denmark and Norway, and they are also reliable with the compliance rate stated in our study[66].

[66] Our study further exploits the more detailed results of the Eurotrak survey as for satisfaction and quality of life.

Table 26 – Overall satisfaction of users (7 possible answers, from 'very unsatisfied' to 'very satisfied': satisfaction = total of 3 satisfaction groups – enough, well, very well)

	France	Switzer-land	UK	Germany	Denmark	Norway	Italy	Japan
Overall satisfaction 2009	86%	-	77%	72%	-	-	-	-
Overall satisfaction 2012	80%	84%	72%	77%	70%	72%	70%	36%
Overall satisfaction 2015	84%	81%	70%	77%	-	-	79%	39%

Source: EHIMA, 2015

As underlined by the IGAS (2013), it is best to remain careful when interpreting this satisfaction score, which also reflects socio-cultural differences and collective preferences. Similarly, a score function cannot be transposed from one country to another, and in the framework of a quality of life assessment which relies on a preference-based questionnaire (such as EQ-5D or HUI3), it is tricky to compare these rates that do not cover the same collective preferences regarding health status. It would be more interesting to observe, country by country, preference variations, but data are insufficient to state a trend.

Empirically, it is however interesting to underline the presumed link between the compliance index (inverse of equipment rotation rate for the eligible hearing aid population) and the satisfaction rate (Godinho, 2015b). The author linked this index with the overall satisfaction rate in 2012. Apart from Italy, he observed a close relationship between satisfaction rate and compliance rate: where the satisfaction rate drops from 80% (France) to 72% (United Kingdom), the compliance index is 2 times lower. Two groups of countries are identifiable: Switzerland-France-Germany characterised by both a performant satisfaction rate and compliance index; the group Norway-Denmark-United Kingdom where a less performant satisfaction rate is associated with less compliance. Italy has a unique position (with a high compliance index and middling satisfaction). This position is due to a bias in the comparison, because the binaural equipment rate is low (44%) and the access rate particularly low. The compliance would remain high for equipped people, because of insufficient access (OOP remaining high); the choice would be driven towards basic or downmarket devices given the coverage (zero OOP in these cases), explaining only middling satisfaction. As regards the two criteria (compliance/satisfaction), the best group is Switzerland-France-Germany: this analysis reinforces the previous approach in terms of *real* access rate.

The international comparison of Alcimed-CNSA (2009) which focused on traditionally 'Beveridge-type' countries (Sweden, the United Kingdom, Italy, Spain) and a 'Bismarck-type' country (Germany) showed moreover that equipment rates were not only dependent on the financing system but also on cultural factors (southern countries more often renouncing equipment seen as a disability indicator), or else of users' lack of information or the device type (downmarket etc.).

Starting from their statements and from our analysis, the main elements to be underlined are the following:

- The optimal equipment rate in each country is not as standardised as in the previous estimations (for example 50% of hearing impaired people, because of cultural differences between countries, or medical advice or social disability perceptions). Moreover, this rate is likely to change over time. This statement slightly restricts the significance of our estimations;

- A refunded access in France would involve changing the system in a politically radical direction and, moreover, it has been observed that free access in National Health Systems is associated with a lower compliance and so to a lower efficiency (a weaker result): it is not possible to state if this is a consequence arising from lower user commitment, or if it is an effect of integrated systems which associate free access with access rationing (it is a possible explanation of insufficient adaptation and follow-ups by audiologist), or even if it is an impact of hearing aid quality (downmarket and mid-market ones). The assumption of a lack of interest in follow-ups audiologists and/or organisational barriers to follow-up access should -be favoured here[67] ;

- The issue of decoupling the device and the service by means of separate pricing cannot be discussed regarding other countries included in the comparison. Indeed, it would be necessary to investigate this question by itself. In general, both activities are not dissociated in western European countries (Alcimed-CNSA, 2009). If they were separated, the compliance rate would be affected since the follow-up service is associated to an OOP for patients. Moreover, it would probably generate an extra cost in terms of business activity (relaunches, induced demand), that would be passed on in prices, associated with a risk of activity deviating from various patient needs and which focused instead on their ability to pay. A conventional bounded minimal price for middle-market hearing aids, identical in every place, including the service, is probably a more desirable pathway for users;

- The device lifespan varies between countries, which has an impact on the overall cost for several years. This lifespan certainly depends on financing rules (it is reduced in countries where coverage is large) or on the initial investment cost (the choice of an upmarket device may be associated with a longer lifespan as in France);

- Overall user satisfaction varies between countries yet is quite comparable (apart from Japanese people whom subjective assessment of health status is structurally lower than those in other countries – OCDE, 2015). This satisfaction rate seems to be linked to the compliance rate, and so probably to the audiologists' counselling service, since the device performances are likely to be similar according to what experts say (cf. infra, section 4). The market line of devices may also play a role;

[67] In accordance with our previous analysis on hearing aid pricing.

- It is important that the user can *in* fine choice their preferred device in order to sustain a better compliance (thanks to a fixed price users' preferences and their willingness to pay). A higher reimbursement of downmarket or middle market devices ensures user's solvency and allows this trade-off;

- Compliance depends closely on device suitability to needs, which relies on the audiologist's role (however, bias in this counselling and advice is possible in the case independent, non state-salaried practitioners);

- Compliance depends closely on adaption and follow-up and, thus, impose to deliver information next to the user, about the device and the added-value of audiologist's counselling (that are more often billed on an *ex ante* basis in all the countries) ;

- the added-value of upmarket devices should be more fully discussed in scientific literature, in order to dissociate the effect 'high technology' and the effect 'quality of service' in patient satisfaction. According to the different hearing aid market lines, the issue of lack of information about added-value is a major impediment in the assessment of their relative utility;

- geographical accessibility of hearing aid centres as well as access delays to follow-up appointments have to be analysed through the issues of compliance and counselling. It is also necessary to study access via references from prior consultations with ENT physicians and general practitioners (and particularly the medical demography);

- the lack of information and monitoring *a posteriori* of ENT's or GP's medical recommendations and advice is a common feature in countries, which limits the possible field for equipment assessment.

The significant growth of equipment rate in France during the last few years seems to demonstrate the impact of technological improvement on the preferences of eligible people for hearing aids:

- they increasingly access hearings aids despite the price to pay;
- hearing aid miniaturisation and their low-visibility leads to better access and make it commonplace, even for younger people with the spread of connected hearing aids.

The main obstacle to hearing aid access in France (financial barrier) questions current financing rules, and particularly the public trade-offs that have led hearing aids to be classified in the 'low risk' category and practically out of socialised health care. This classification implicitly indicates that the hearing aid is a luxury product whose medical added-value is very low: in comparison to the trade-offs for drug classification, the hearing aid medical added-value ranges between 'low' and 'insufficient', since its observed reimbursement rate is under 15%.

Yet, wide access to hearing aids (2/3 in terms of 'real access' of the eligible population) shows clearly that demand elasticity is low: they are a necessary item. In general, the public choice of coinsurance depends on the combination of 'low risk' and 'commitment'. There is only partial reimbursement in relation to 'low risk', or even totally excluded from the social health care basket when it does not depend on the collective responsibility and implies an individual

judgement on the trade-off consumption-price (in order to avoid over-consumption or, in economics, the 'moral hazard' risk). Yet, not only is access significant despite the OOP payment, but moreover – contrary to optics – its health consequences as well as its economic impact are likely to be major. The cost to society of hearing aid renunciation, in terms of quality of life, expenditure and social inequalities is in total opposition to the objectives assigned to the French health system.

The survey of scientific literature which follows in the next section will shed light on the link between hearing loss and people's morbidity-mortality rate, allowing to estimate the burden of illness.

2 Health and economic consequences of hearing loss: impact study

Nowadays, hearing loss is considered as a major public health issue in the scientific literature and by international health agencies. The World Health Organisation (WHO, 2016) estimates that the burden of illness actually concerns more than 5% of the global population, namely 360 million people, and one third of the population aged over 65, with a dominant prevalence in low- and middle-income countries[68]. Since hearing loss prevalence is rising with age, actual ageing of the global population would else increase this prevalence, with an over-representation of moderate to total hearing loss.

It is the most frequent sensory deficiency, leading to a great degradation of quality of life, which is associated with substantial economic and societal costs. The main consequences of hearing loss are due to the decrease in communication and human interaction, which has an impact upon mental, psychological and cognitive dimensions of the person's health status. These consequences have been known for a long time, as in 2006 Shield reviewed them, showing that psycho-social effects were already being referred to in1979. The main dimensions of well-being (in the actual assessable sense, namely health state, wealth and education/qualification level) affected by hearing loss and referenced by the author are: global quality of life; loneliness, social isolation and exclusion; psychiatric disturbance and depression; family relationships; stigma and low self-esteem; education; difficulties in particular environments; general health estimated in terms of doctor's consultations; cognitive skills and dementia; memory loss; intimate relationships; prejudice and abuse; employment; all these dimensions are also associated with denial for a fraction of impaired hearing people.

Causal relationships between hearing loss and each of these dimensions are better recognised and quantified in the recent literature. Give that this this literature is abundant, we propose a survey of the main papers on this topic (and not a systematic review of the scientific literature). Moreover, we have selected papers specifically focused on the elderly, but with a specific inclusion of papers questioning the link between hearing loss and professional situations for the adult workforce.

2.1 Observed scientific connections between hearing loss and morbi-mortality in adults and elderly populations

In the international literature, numerous papers study the connection between hearing loss – one of the most frequent chronic health status for elderly – and several morbi-mortality indicators. Thus, hearing loss is independently associated with mortality, heart attack, ischemic heart disease, diabetes, and smoking[69]. Also, it is established that hearing loss is

[68] The WHO (2016) defines hearing loss as an impairment implying at least a loss of 40 dB in the best ear for adults and 30 dB for children.

[69] The independent association means here that age impact effect is controlled.

associated with functional, physical and psychosocial deficiencies, or else with a lower quality of life, an increased risk of institutionalisation, falls, cognitive decline, car crashes, and even lesser ability for personal health empowerment[70]. In other words, the burden of illness is likely to be heavier for hearing impaired people, not only because of the hearing degradation which decreases communication capacities, but also for associated morbi-mortality. In the literature, the connections that are mostly recorded for the elderly and for which a presumed causality is stated, concern mortality risk, mental health degradation and cognitive decline. Hence, our review will be primarily focused on these issues. Secondly, we will bring up the connection between hearing loss, labour market integration and social relationships/leisure activities.

2.1.1 Hearing loss and associated limitations in France

In order to assess the extent to which activity restrictions (daily, professional and leisure) depend on auditive functional limitations (AFL, cf. supra), it is important to differentiate the latter from other associated deficiencies and functional limitations. This analysis has been driven by the DREES (Haeusler et al., 2014; Haeusler et Mordier, 2014), which distinguishes, on the one hand, deficiencies associated with AFL and, on the other hand, functional limitations – apart from auditive ones - related to these deficiencies.

2.1.1.1 Associated deficiencies with hearing loss

In 2008, given a similar age and sex, 77.4% of people affected by moderate to total AFL stated that they had at least one another associated deficiency apart from auditive, being either motor, visual, intellectual, cognitive, or other (against 63.3% in the general population). This rate is clearly different since moderate visual deficiencies[71] are excluded from the field, given that they almost equally concern both populations (i.e. moderate to total AFL / general population): indeed, 68% of people affected by moderate to total AFL declared, in 2008, that they had an associated deficiency, against 37% of the general population.

The most significant gaps that can be observed regarding the standardised rate are:

- ***Motor deficiencies: 35.1% against 20.3%;***
  - Significant discomfort in joints (24.3% / 14.5%);
  - Muscular strength limitations (14.7% / 8.3%);
  - Balance troubles (12.3% / 5.2%);
- ***Deficiencies relating to speech: 8.9% / 2.5%;***
- ***Psychological, intellectual, cognitive deficiencies: 39.3% / 20%***
  - Significant memory troubles (10.1% / 4.8%);
  - Mood troubles (19.7% / 8.7%);
  - Anxious troubles (23% / 12.6%);
  - Difficulties in relationships with others (10.8% / 3%);
  - Understanding difficulties (7.9% / 2%).

[70] Cf. for example Karpa and al. (2010) or Archbold and al. (2014).
[71] Defined as the "difficulty to see closer or further, but neither blind, nor visually impaired".

As concerns motor deficiencies as well as psychological, intellectual and cognitive deficiencies, the gaps between both populations were found at all ages. Greatly higher anxiety troubles and mood troubles are a notable characteristic for hearing impaired people.

2.1.1.2 Functional limitations associated with hearing loss

46% of people affected by moderate to total AFL had declared another associated functional limitation (against 20% of the global population). These associated deficiencies could be visual, motor, psychological, intellectual as well as cognitive, and some of them could be the direct consequence of hearing loss, particularly learning or understanding activities: as an illustration, it can be seen that learning difficulties or memory troubles were 3 times more frequent than in the global population (table 27).

Table 27 – Prevalence of functional limitations apart from auditive for people affected by moderate to total AFL compared to general population (2008)

	Number of persons concerned among the people affected by moderate to total AFL	Gross rate	Standardised rate	Overall Population
At least one important limitation linked to eyesight	**436000**	**8%**	**5%**	**3%**
To see print characters (possibly with glasses or lenses)	353000	7%	4%	2%
To see a face at 4 meters (possibly with glasses or lenses)	243000	4%	2%	1%
At leat one important limitation linked to moving	**1407000**	**26%**	**14%**	**8%**
Able to walk 500 meters on flat ground without help or cane	838000	15%	7%	4%
Able to go up and down a floor of stairs without help or cane	940000	17%	7%	5%
Able to carry a 11 pds bag of supplied for 10 m without help	1140000	21%	11%	7%
At least one important limitation affecting the upper body	**618000**	**11%**	**6%**	**3%**
Raise the arm	601000	11%	4%	2%
Use his/her hands and fingers in order to take an object	537000	10%	2%	1%
Take an object with his/her hands without technical help	195000	4%	2%	1%
Other important motor limitation				
To bend down or to kneel down without help	1310000	24%	11%	7%
At least one important psychological, mental or cognitive	**999000**	**18%**	**17%**	**8%**
Not able to remember what time of day it is	145000	3%	2%	1%
Memory lapses during the day	303000	6%	5%	2%
Difficulties to concentrate for more than 10 minutes	230000	4%	6%	2%
Difficulties in daily life (find his/her bearings on an itinerary, add up money)	331000	6%	5%	2%
Difficulties to learn new knowledge or know-how	440000	8%	7%	3%
Difficulties to understand others or to be understood	217000	4%	6%	1%
Imperilment (out of imperilment caused by eyesight problems	146000	3%	3%	1%
Too impulsive or agressive	259000	5%	6%	3%
At least one another important limitation	**1126000**	**21%**	**9%**	**7%**
To bite and chew hard foodstuffs	984000	18%	8%	6%
To control his/her stool and urines	333000	6%	3%	2%
At least one important functional limitation	**2507000**	**46%**	**32%**	**20%**
Overall	**5433000**			

Key : 363,000 persons, 6.7% of people affected by moderate to total AFL have many difficulties or cannot see at all printed characters of a newspaper. Standardised by age and sex, i.e. eliminating the differences due to demographic structure, this rate is at 4.1% against 2.1% for the whole population

Source: Haeusler, Mordier, 2014

The functional limitations that were most frequently declared are those related to exterior displacements. Psychological, intellectual or cognitive limitations affected 18% of hearing impaired people, often occurring through memory lapses, concentration difficulties, learning

new knowledge or know-how difficulties, or else difficulties to make themselves understood or to understand others.

2.1.1.3 Activity restrictions and social involvement associated with hearing loss

For France, the study of Haeusler and Mordier (2014) showed that involvement in social life is only reduced for people affected by heavier AFL, and in general activity restrictions were mostly related to non-hearing limitations: of 19 daily restrictions, the two main situations – for severe or total AFL – were the independent use of a phone and call for emergency services. For people aged over 60, access for assistance in daily activities is higher when people are affected by moderate to total AFL (35% against 22% for people not being hearing impaired), but the accumulation of several health troubles, functional limitations and the ageing effect makes it arduous to highlight a causal relationship between hearing loss and autonomy loss: very severe to total AFL are associated with an autonomy loss, itself leading to a more important access to assistants. However, this access is not only due to AFL severity but also to associated functional limitations.

People with AFL who are in the work force differed from those in the general population by having a lower level of qualifications: the more severe the limitation, the lower the qualification. As for employment access, the activity rate of people being affected by moderate to total AFL was similar to that in the general population, indicating an improvement in occupational integration over a decade. However, the severity level of AFL had an impact on the opportunities to aim for managerial positions.

Moreover, the same study showed that social relationships, being estimated by the likelihood to live as a couple, were not impacted by the hearing trouble except in very severe or total AFL, and nor were social relationships, being estimated by the frequency of familial or friendly meetings: the frequency of friendly meetings reduces with age, independently of involved AFL. Nevertheless, these favourable results have to be considered with caution, to the extent that the quality of conversation and their dependency on AFL level could not be measured.

The French study also showed that the boundary of leisure activities for people affected by AFL is reduced, with a notably lower involvement compared to the general population (81% for AFL comprising all severity levels, 55% for moderate to total AFL and 90% for the general population). The impact was particularly clear on activities such as “listen to music” (62% against 83%) and “go to the cinema”: the probability of going to the cinema was reduced by 30% in cases of moderate AFL and by 50% in cases of severe to total AFL (Haeusler and Mordier, 2014). It should be underlined that “*for people over 60 years, hearing troubles do not have an impact on the number of leisure activities practiced*”[72].

[72] p. 15.

2.1.2 Main findings in medical scientific literature

The main recent findings in medical scientific literature have shown the association between hearing loss and risks of mortality, many mortality risk markers, falls, degradation of mental health, and cognitive decline for older people over 50. They have also highlighted the difficulties encountered on the labour market for working people. Finally, they have demonstrated the positive impact of hearing aids on the risk of health status degradation.

2.1.2.1 An increased risk of mortality

For people aged 50 over and over, studies have shown an increased risk of mortality for those affected by moderate to severe hearing loss compared to the general population.

In 2010, Karpa et al. demonstrated, on the basis of statistical analysis of 2,956 Australians aged 50 and over, followed for 13 years, that hearing loss (hearing thresholds greater than 25 dB) was associated with increased risk all-cause mortality after adjustment for age and sex[73]. This risk was mediated by cognitive impairment, walking disability and self-assessments of health, that increased mortality directly and indirectly. The study was however able to reveal a connection between the degree of hearing loss severity and an increased risk of mortality.

The observation of a connection between hearing loss and increased risk of all-causes mortality is also stated by Fisher et al. (2014), on a population-based cohort study: the aim of the study was to analyse the link between, on the one hand, hearing impairment only, visual impairment only, both associated impairments and, on the other hand, all-causes mortality and cardio-vascular diseases. The population involved 4,926 Icelandic people aged over 66, followed on the basis of their examinations between 2002 and 2006 and then followed prospectively by survey until 2009 for mortality. Impairments ranged from moderate to greater. Hearing loss prevalence is estimated at 25.4% in the sample. The main results showed: 1) an all-causes mortality significantly greater for hearing impaired persons (after adjustment by age), particularly for men and particularly from cardio-vascular causes[74]. Mortality rates for women were not significant, although they were greater than those in the general population. 2) Men and women being fitted with hearing aids tend to be older and more severely impaired than others. However, their risk of mortality is lower, and this has an impact upon the global result for all the people with hearing impairment (in other words, hearing aid access reduces the mortality risk, and this reduction reduces itself the gap in mortality risk compared to the general population). The assumption made by the authors is the following: hearing aid equipment reduces social isolation and increases neurosensory stimulation.

The study of Genther et al. (2015) strengthens these results, by analysing an American population-based cohort of 1,958 older people aged over 69 during 8 years after audiometric

[73] Two statistical models used by the authors confirm the association: in the Cox model, the OR* is 1.39, (CI95% 1.11-1.79); in the structural equations model, the OR* is 2.58 CI95% (1.64-4.05).
[74] On the basis of two statistical models, the OR* for men is 1.74 (CI95% 1.21-2.49) and 1.93 (IC95% 1.30-2.87).

examination. With control of demographic and cardiovascular risk factors, they showed that hearing impairment (> 25 dB in the better ear) was associated with a 20% increased mortality risk compared with normal hearing[75]. The authors suggested investigating the pathways leading to this association and in order to determine the impact of rehabilitation hearing strategies.

All these papers recommend taking into account this association between hearing impairment and mortality risk in medical follow-ups, which implies that a part of this risk is preventable and causes loss of life in years.

2.1.2.2 An increased risk of falls

The INSERM recommendations (2014) for preventing falls amongst the elderly estimated that a hearing loss of at least 25 dB was associated with a threefold increase of risk for falls, due to the deterioration of sensory function, the loss of sound marks contributing to balance, and the reduction in cognitive resources ensuring balance and attention.

This possible link has been studied by Viljanen et al. in 2009 and by Lin and Ferrucci in 2012. Viljanen et al. (2009) analysed the predictive value of hearing impairment as a fall factor through a sample of 217 pairs of female Finnish twins – monozygotic and dizygotic – aged 63-76 years. They showed that people with poor hearing acuity (loss of at least 21 dB in the better ear) have a higher fall risk, because of their poorer postural control among other factors.

Lin and Ferrucci (2012) studied a population of 2,017 persons aged 40-69 years, from 2001 to 2004, based on the American register NHANES. They showed that hearing loss (> 25 dB) is significantly associated with the risk of reported falls. Moreover, this risk increased with hearing loss severity (1.4 fold by 10 dB classes), independently of demographic factors, cardiovascular factors and vestibular balance.

2.1.2.3 A degradation in mental health

The connection between hearing loss and mental distress has been highlighted by a great number of studies.

The analysis proposed by Fellinger et al. (2007) of 373 members of the German Hard of Hearing Association of all ages showed that people affected by moderate to severe hearing loss (even total) had worse psychological scores in contrast to a non- hearing impaired population: using the WHO's brief quality of life (WHO-QOL) the scores are similar in both populations ; through the scale 'BSI' (*Brief symptom inventory*), people affected by moderate to severe hearing loss suffer from greater anxiety, somatization, paranoid ideation, and depression (the level of degradation depends on severity). This study also showed that these people have worse social relationships compared to the signing deaf (evident in the scales of both the WHO-QOL and BSI). The authors compared the levels of psychological distress and quality of life and suggested two main conclusions: on the one hand, general psychiatrists

[75] OR* 1.20 95%IC (1.03-1.41).

should consider the increasing risk of isolation and quality of life degradation for hearing impaired people who have communication difficulties or who lip-read (compared to the signing deaf); on the other hand, the benefit of hearing aid equipment could be substantial since they would improve their communication capacities (for more profound hearing loss, the benefit would rely on cochlear implants).

Moreover, the study of Bernabei et al. (2011) has shown that the accumulation of a hearing impairment and vision impairment in an Italian study population (7,389 older people) is associated with depression and anxiety. More recently, through research in the United-States, Li et al. (2014) have estimated the prevalence and risk factor in depression for adults older than 69 and being affected by hearing loss (among 18,318 persons participating in a national survey). Depression was assessed on the basis of a customised scale, and results showed a significant association between hearing loss and depression, particularly for women, and especially in the case of moderate hearing loss. At the same time, Acar and al. (2011) analysed the results of a study involving 34 Turkish people older than 65 in order to estimate the impact of hearing aid equipment on mental health: they showed that the use of hearing aids for 3 months significantly improved psycho-social health state, as described by the MMSE scale.

In the same perspective, in 2013, Mener et al. worked on the cohort NHANES data, for two periods (2005-2006) and (2009-2010), including a population aged 70-79 to whom a specific questionnaire assessing depression was proposed (PHQ-9). They studied the impact of hearing aid use (at least 5 hours a day) and showed a significant reduction of symptoms of depression and major depressive troubles. This favourable impact was appreciable starting from the first 3 months of equipment. However, the authors underlined that it wasn't possible to state if this association would result in a larger inclination of people without depressive trouble to access for hearing aids, or if their perception of their own psychological frailty would have led them to access for hearing aids. Hence, the authors suggest future scientific investigation in order to question the link between hearing aids and the reduction in depressive symptoms.

For France, the studies of the InVS and the INPES (Sitbon and al., 2015) undertaken as part of the the framework of the « Baromètre santé sourds et malentendants » (BSSM – 'Barometer for the health of deaf and hard of hearing people') in 2011-2012 underlined the degradation of mental health for people affected by deafness and hearing troubles. They highlighted the more frequent rate of suicidal thoughts than in the general population (Baromètre santé 2010, BS): suicidal thoughts occurring during the last 12 months were 5 times more frequent (affecting indeed 22% of people in the NSSM survey against 4% of the general BS survey), whereas the number of suicide attempts during the life course were 3 times higher for men and twice for women. The analysis by sex and age groups showed a decrease in suicidal thoughts with age: 15% of men and 17.2% of women aged 55-75 had these thoughts against 35.4% of men and 25.3% of women aged 15-24. Retired people (13.4%) less affected than professionally active people. Moreover, the comparisons between the two surveys showed that indicators relative to physical violence (6.7% against 2.8%), dismissive or humiliating looks or words (26.4% / 14.9%) or sexual violence (20.4% / 8%) are obviously higher. The research of the causes leading to psychological suffering resulted from tiring communication situations and hardness of hearing troubles. Situations of psychological violence can also participate in the deterioration of psychological health. Indeed, everyday life characterised by a deterioration in communication quality and social relationships because of impairment would

be likely to generate 'conflictual interactions', 'isolation, feelings of exclusion and discrimination'.

Vulnerability, which is linked to physical and psychological suffering, led the authors to recommend reflection concerning access conditions for technical and human assistance, as well as an awareness campaign for hearing impaired people and for the general population in order to promote positive change of representations and prejudice, or even for health professionals (dealing with pain, and dealing with psychological suffering).

2.1.2.4 Deterioration in cognitive capacities

The papers of Lin et al. (2011a; 2011b; 2013 ; 2014) are among the most cited articles in the field of research into the link between hearing loss and cognitive decline. In 2011(a), Lin et al. tested the assumption in which hearing loss is associated with all-causes dementias and with Alzheimer's disease. They based their study on a population of 639 Americans followed prospectively since 1990-1994 (inclusion period) when they didn't have dementia, with a follow-up of 11.9 years (median time) during which 58 cases of dementia were diagnosed, including 37 cases of Alzheimer's disease. The authors showed that dementia risk increases significantly and linearly with hearing loss severity. The risk of Alzheimer's disease increased at such a confidence interval that it was not possible to validate the association assumption. They concluded that hearing loss is associated independently with all-causes dementia, without being able to say if hearing loss is an early marker or is a modifiable risk factor.

The studies also released in 2011 (b) by Lin et al. analysed the link between hearing loss and cognitive decline on the basis of a cohort of 347 persons aged 55 and over, who were in the same panel cohort BLSA (Baltimore Longitudinal Study of Aging), and who had neither hearing loss nor dementia during the inclusion period 1990-1994. The authors showed that the more hearing loss increases, the more the scores on the mental health scale (MMSE) deteriorate, as well as memory and cognitive function: when hearing performance is reduced by 25 dB, the scores converge to those of a population without hearing loss who are older by 6.8 years. In other words, hearing loss accelerates the cognitive ageing process.

The study of 2013 assumed that hearing loss was independently associated with an accelerated cognitive decline. There were 1,984 American adults, aged on average 44.4 years, followed since their inclusion in 1977-98 for 6 years. Hearing loss concerned 1,162 persons, for whom cognitive decline rate – measured through 2 adapted scales – appeared to be 41% or 32% according to the 2 scales. Finally, the authors stated that people with hearing loss have an increased risk of cognitive deficiency of 24%[76], these latter rates and this risk being linearly associated with the severity level of hearing loss. They concluded that hearing loss is independently associated with accelerated cognitive decline and they then suggested an assessment of the impact of auditive rehabilitation on these results.

In 2014, Lin et al. estimated the association between hearing loss and brain volume changes for the older people included in BLSA panel and they confirmed the independent association

[76] OR*: 1.24 CI95% (1.05-1.48).

between the two measures: hearing loss beyond 25 dB led to an accelerated atrophy of the whole brain and in particular the regional volumes concentrated in the right temporal lobe.

The very recent meta-analysis of Schmulian Taljaard et al. (2015) on the issue of a causal relationship between hearing loss and cognitive decline included 33 studies related to 40 population samples. It concluded (with some reserve on the sample size and on the lack of control on risk factors) that:

- Cognitive capacities are significantly lower for people with non-treated hearing loss, and and remain lower for hearing aid equipped people regarding people without hearing loss;
- The degree of cognitive decline is significantly associated with the level of hearing loss for both people being equipped and not being equipped with hearing aids;
- Auditive intervention significantly improves cognitive capacities;
- Hearing loss has an impact upon all cognitive domains.

If several papers have stated a significant connection between hearing loss and cognitive decline, the analysis of Amieva et al. (2015) showed the favourable impact of hearing aid equipment in reducing this adverse effect. The study was based on the prospective cohort ('Personnes âgées' QUID), whose population was studied from 1989-90. The cohort involved 3,670 older people (65+) at the moment of the study. Hearing loss was assessed through a perception questionnaire recording the moderate or major difficulties relating to hearing capacity. Cognitive decline was assessed by the MMSE scale, recorded during follow-up consultations. The authors also showed an independent and significant association between hearing loss and cognitive decline. Above all, they showed that decline depends on the use or not of hearing aids, which can delay it: indeed, people using hearing aids have the same cognitive decline than people without hearing loss.

In a similar perspective, Dawes et al. (2015) examined, on the basis of English data (164,770 persons aged 40-69 whose hearing capacities were recorded) the impact of hearing aid use on cognitive performances, social isolation and/or depression). Using a model, they showed that hearing aids are associated with a better cognitive performance, independently of social isolation and depression; these hearing aids are not here stated factors of improved cognitive capacity, but thanks more to direct improvement in hearing and personal efficiency. The authors suggest supporting access to hearing loss treatment in order to reduce the burden of disease related to cognitive decline and quality of life.

Meanwhile, the paper of Hung et al. (2015) focused on Alzheimer's disease and relied on a controlled study including a sample of Taiwanese over a 13 years' period and where 488 persons aged over 65, with a diagnosis of Alzheimer's disease, were matched with 1,952 persons without Alzheimer's disease in the control group. The aim was then to compare comorbidity factors (including hearing loss) with the risk of having Alzheimer's disease in both groups. The statistical analysis showed that hearing loss is associated with an increased risk of Alzheimer's disease in an older population with an odds-ratio of 1.39[77].

[77] Interpretation: individuals being affected by a hearing loss have 1.39 times more risk to have an Alzheimer's disease, as the confidence interval does not comprise the value 1 (1.05-1.84). However, the association does not prove the causality, even a presumption exists today.

2.1.2.5 Health at work

In France, the recent analysis of Sitbon et al. (2015) of BSSM have given some key data on the impact of hearing loss on health at work:

- Hearing impaired people more frequently suffer at work, as 34% of this working population is in a psychological distress situation due to working conditions (in contrast to 5.4% of general working people), 10.3% of them have thought of suicide during the last past 12 months because of their working situation (1.4% for the general population) and 3.5% have attempted to kill themselves during their lives for the same reasons (0.6% for the general population). Moreover, comprehension difficulties are frequent, in the double sense of being understood by and to have understood colleagues;
- 2/3 of this population have asked for a recognition of their impairment ('RQTH' benefit).

Although the 'Handicap-Santé' survey 2008 did not reveal any major difficulty in terms of professional integration (cf. supra) – which could be interpreted as the result of social progress over a decade- the observed results in developed countries are more mixed: in the United-Kingdom it can be observed that the person's situation in the labour market is affected in the case of hearing loss with regard to career opportunities, the loss of employment, and difficulties to get back to work (Archbold et al., 2014). Access to hearing aids would alleviate this negative impact.

Whether mortality or morbidity, French as well as international scientific literature highlights the consequences of hearing loss, which are likely to be substantial for the hearing impaired persons themselves, not only in terms of quality and quantity of life, but also in terms of economic and societal impact (burden of illness): if hearing loss is independently connected to other health state dimensions - physical, psychological, cognitive, social - , it is then associated with an economic burden in terms of medical and non-medical direct costs, indirect costs (productivity) and intangible costs. Access to hearing aids would reduce this burden – recent scientific studies increasingly tend to demonstrate this assumption. The aim of the following section is to explore this issue.

2.2 Economic impact of hearing loss

As shown in the first section of this report, most French agencies (HAS, 2008; HCAAM, 2008; CEPP, 2008 ; IGAS, 2014) have pointed out the lack of global assessment of hearing aid expected service (particularly on the possible differences of quality rendered by hearing aids according to their characteristics). However, the HAS (2008) specified that "*the benefit of the prosthesis is linked to its suitability with the audiometric characteristics and the patient's way of life, as well as the quality of its adaptation performed by the audiologist*"[78]. The HCAAM

[78] p. 9.

(2008) estimated on its side that the question of medical devices recorded on the LPPR is tricky to the extent that "*the rendered service is hardly assessable*" because it depends both on the apparatus and the service[79].

Moreover, the continuous innovation concerning hearing aids leads to a rapid replacement of the products on the market, upmarket products becoming five years later downmarket or middle market products, whereas the least performant exit the market, resulting in a 100% digital supply (Alcimed-DSS, 2011). In this way, device assessment is increasingly complex, in terms of separating added-value from marketing innovation. As underlined in this report, such an assessment is still necessary to put in perspective reimbursement rules for hearing aids.

This question is also raised in the international literature: two systematic reviews were undertaken in 2015 by the Cochrane Library, but their results were not yet released at the time of this report. The research protocol of Ferguson et al. (2015) specifies that the main medical action in the face of hearing loss is compensation with hearing aids, but we don't know their exact performance, which is 'user dependant', to use the CESE's term (2015), although 11 million hearing aids were sold in one year. The main objective of hearing aid users affected by moderate to severe hearing loss is obviously to reduce the sensory impairment, but also to reduce, indirectly, associated limitations. If it is possible to assess the patient's hearing capacities by means of physical measures (audiometric ones), the consequences in terms of associated limitations could be assessed by using questionnaires specific to the associated disease/limitation (for example, MMSE in the case of mental health) or by preference-based generic questionnaires for quality of life. However, the latter may not allow, in general, the demonstration of the real benefits of hearing aids because of the low impact multiple consequences have on them. This is apart from the HUI3 questionnaire which includes a question directly linked to hearing loss level (cf. infra). Ferguson et al. point out the lack of scientific consensus on this issue and, further, the lack of a measure reference on the benefit in terms of quality of life, and even the lack of systematic review of recent literature (particularly that which would highlight results of prospective randomised controlled trials). All this considerably limits health policies towards a roadmap for hearing aid regulation and delivery, and it also limits the possibility to define a guideline for their prescribers.

Taking into account this statement, our analysis will propose an assessment scenario which does not pretend to be an efficiency analysis and which must be read with caution, but that would give some general orientation on this issue. Before beginning, we propose a brief overview of several papers focused on the link between hearing loss and health care access.

[79] p.3.

2.2.1 Economic assessments in scientific literature of hearing loss: health care access, expenditure and screening

On the basis of previous articles which have demonstrated an independent connection between hearing loss and the morbi-mortality of older people, some papers have tried to estimate the impact of health degradation related to hearing loss on heath care access and expenditure level. Others papers have considered the benefit that would be expected of an earlier screening of hearing loss.

2.2.1.1 Higher health care access and expenditure level

Two recent papers, relying on results from previous international studies, have focused on the economic impact of a degraded health state for hearing impaired older people to heath care access and expenditure.

Genther and al. (2013) have identified an association between hearing loss, hospitalisation and burden of illness for older people aged over 69 (representing 2/3 of hearing impaired people and 1,140 people who were matched with 529 persons without hearing loss) for two different periods: 2005-06 and 2009-10. The statistical analysis showed a significant association between hearing loss and several markers of health care pathways and health states: the occurrence of hospitalisation, the number of hospitalisations, and the number of days with worsened physical and mental health. However, the connection with an inactivity related to health state was not stated. It showed that hearing loss is independently associated with hospital access and so with an increased use of health care services, which could be explained by social isolation, and by the effects of hearing loss on cognitive decline and dementia (these factors were controlled in the analysis of healthcare pathways). The authors suggested that an analysis should be pursued of the effect of auditive rehabilitation on hospitalisation reduction and self-assessment of health state.

In Foley et al. (2014), the question was to investigate the nature (independent or not) of the connection between hearing loss and the higher level of health expenditure. The study used expenditure figures for 34,981 persons aged over 64, who had completed the Short Form 12 quality of life questionnaire. Health expenditure was assessed regardless of financing type, to which were added a non-monetary estimation for health state results (number of assistance days, quality of life scores). The main results in this study showed, that for a hearing loss prevalence ranging around 23.7%, the probability of higher expenditure was significant (the extra amount was significant - a 39%)[80], meaning on average US$ 392, because of more often medical visits, outpatient and emergency hospitalisations. The scores for quality of life were lower in the physical and mental dimensions compared to people without hearing loss. The authors concluded that there was an independent association between hearing loss and a higher level of expenditure: this would represent an extra amount of US$ 3.1 billion for all hearing impaired people (7.91 million people), related to falls, cognitive decline, depression and social isolation. They also considered that this estimation was probably an under-estimate

[80] Extra health expenditure proportion: OR* 1.39 CI95% (1 .12-1.71); extra health expenditure amount: OR*392$ CI95% (277-513).

because of hearing loss denial in surveys. As with previous authors, they suggested the impact of auditive rehabilitation strategies on health care expenditure reduction should be studied.

These suggested auditive rehabilitation strategies would involve earlier screening for hearing difficulties and, thus, an improvement in access to hearing aids since economic studies will have demonstrated their favourable cost-effectiveness ratio.

2.2.1.2 Economic concerns of earlier screening for hearing loss

As shown previously, hearing loss is common after the age of 50 years, with increasing prevalence and severity with ageing. Autonomy as well as quality of life's people would be jeopardised if hearing loss is not compensated.

The English literature has shown that individuals often wait for 10 to 15 years before accessing hearing aids, because they considerer that their hearing level is not so bad and because they don't envisage themselves with a hearing aid until it their hearing has seriously deteriorated. This is also a result of the misreading of the connection between hearing loss and long term health state: indeed, it is actually stated that hearing aids improve social integration and quality of life, even in the case of moderate hearing loss, and mainly when they are used earlier by individuals.

Is secondary prevention of hearing loss economically reliable? In order to justify a systematic screening process, this hearing loss must become a significant public health priority, associated with a precise knowledge of the 'natural' history of hearing loss and the evidence-based efficiency of earlier screening. Yet, the previous statements highlight not only the significant prevalence of this health state problem, but also its adverse consequences since the link between severity and age has been demonstrated. Screening aims to reduce the hearing impairment impact timeline and its severity impact in a patient's life. Furthermore, this raises questions about the cost of such systematic screening: indeed, a secondary prevention campaign could require significant financial means. The financial requirements would depend on the method, as a systematic screening during the GP's consultations in France would represent little financial outlay to be efficient. Indeed, on the basis of Amieva et al. (2015), screening of the PAQUID cohort was realised over the course of follow-up consultations, by recording a very short questionnaire allowing hearing loss screening. The questionnaire comprised two questions:

- *Do you have hearing trouble?* (possible responses: "I do not have hearing trouble"/ "I have trouble following the conversation with two or more people talking at the same time or in a noisy background"/ "I have major haring loss");
- *Do you use a hearing aid?* (possible responses: yes/no)

Such a questionnaire is easy to carry out during a general consultation without burdening the GP's time. That's why a reflection about this screening method in general consultation deserves to be studied, linked with the 'ROSP' system (the French payment for performance system).

In the literature, most analyses suggest the implementation of hearing loss screening for adults aged 50-65, i.e. an audience who are sufficiently old to represent an important target regarding prevalence but young enough to benefit from earlier screening. However, these

recommendations are rarely assessed regarding efficiency and the economic literature is still sporadic on this issue. We present the main results of two studies on this topic, but we underline that other efficiency studies do exist on the specific economic impact of cochlear implants (not part of this discussion).

1- The study of Davis et al. (2007): hearing loss screening is acceptable and beneficial for people aged 55-74, and a target screening of people aged 60-70 for a bilateral hearing loss of at least 35 dB is the most appropriate.

The authors have considered adult bilateral hearing loss, having consequences on hearing and communication (1/5 of this population), associated with difficulties hearing in a noisy background. If they assess that one in ten people would benefit from hearing aids, one in six hearing aid equipped persons did not benefit from them (no efficacy). Moreover, individuals whose hearing capacities were assessed admitted to having hearing trouble for at least 10 years, were aged 75 on average and had hearing loss considered as severe. This later access leads to more difficulties in terms of their own adaptation because of impairment severity and is associated with reduced communication capacities.

The study of Davis **et** al. aimed to assess the reliability of hearing loss screening by efficient and acceptable methods, in order that this screening be linked to a measurable result in terms of quality of life.

Their preliminary study demonstrated that people aged 54-74 are greatly affected by hearing loss and would benefit from referred to screening. The amplification obtained from using hearing aids clearly improved the health state of people affected by moderate to severe hearing loss (at least 35 dB) when they are screened at least 10 years before the 'natural' point of self-referral for hearing aids. They estimated that the cost-utility incremental ratio ranged around £800 to £1,000 by QALY (Quality adjusted life years, see infra).

2) Early screening efficiently improves the quality of life of older people: the study of Morris et al. (2012)

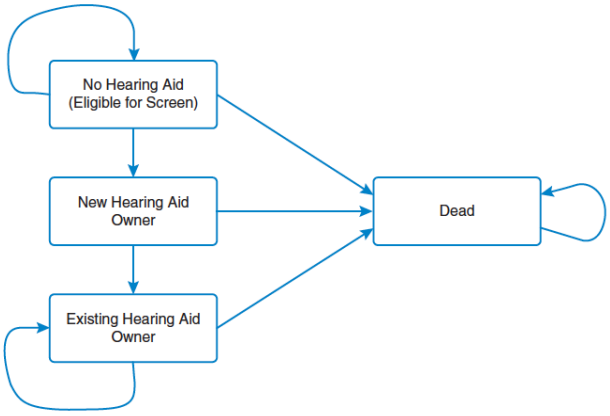
The study of Morris et al. (2012) was largely based on the initial analysis of Davis et al. (2007) and followed its recommendations. In order to set up an economic assessment of screening, the authors compared 3 programs following the English population:

- A 1 step screening program, which targets eligible adults for screening aged 60-70 and invites them to be screened;
- A 2 step screening program, which targets eligible adults for screening aged 60-70, firstly by posting them a questionnaire, then inviting to screening those who has signalled hearing troubles in their answers;
- The self-referral rates through the GP (comparator), who would refer the patient towards an audiometric assessment.

If hearing loss is confirmed (>35 dB), the patient was offered one or two hearing aids, taking into account that individuals could renounce them or might not use them. The model is built around these different scenarios: the framework is a Markov model where cycles last for 5

years, and where cost and utility dimensions are included (utilities are estimated in QALYs, and these values are given in the study of Davis et al.).

Map 1 – Transitions between health states (Markov cycle – 5 years)



Source: Morris and al., 2012.

The main results showed that:

- The 1 step screening scenario dominates (it generates better results than the 2 step screening scenario), thus this scenario is chosen;
- The incremental cost-effectiveness ratio between the one-step scenario and the comparator (self reference to a GP) is estimated to be £1,461 /QALY: it is the price to pay for having one year of good health. It is calculated as the ratio of cost variation and utility variation between the two strategies;
- The differently simulated scenarios linked with a probabilistic analysis show that the dominant strategy is that of one-step bilateral screening of hearing loss from the age of 60, and a delivery of hearing aid equipment starting from 35 dB

The table of parameters and costs presented in the following pages shows estimation ranges related to access to, and use of hearing aids, as well as cost and utility associated with screening (with a utility scale ranging between 0 – worse health state- to 1 – best health state).

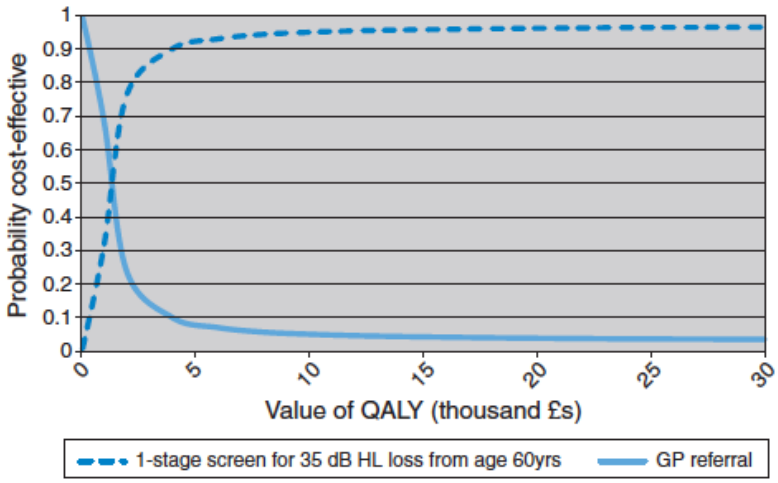
Table 28 – Morris and al. study results of screening efficiency of HL for the English population aged 60-70

Parameter	*Base case*	*Sensitivity analysis range (lower)*	*Sensitivity analysis range (upper)*	*Distribution for PSA*	*Notes*
Prevalence of bilateral hearing loss ≥35 dB HL	Varies from 11.3% (age 60) to 63.5% (age 80)	Varies from 10.7% (age 60) to 46.6% (age 80)	Varies from 14.4% (age 60) to 70.3% (age 80)	Beta	From Davis[9]
Bilateral hearing loss ≥35 dB HL and already own hearing aid	Varies from 6.9% (age 60) to 13.4% (age 80)	Varies from 1% (age 60) to 7.9% (age 80)	Varies from 8% (age 60) to 22% (age 80)	Beta	From Stephens *et al.*[3] and Davis *et al.*[4,9,12,16]
Accept one-stage screen	86%	72%	99%	Beta	Includes those who passively decline by non-response and non-attendance
Accept two-stage screen	56%	40%	87%	Beta	From Davis *et al.*[4,12] and Wilson *et al.*[17]
One-stage screen sensitivity and specificity	Sensitivity 87.4% Specificity 89.1%	Sensitivity 78.7% Specificity 88%	Sensitivity 96.1% Specificity 90.2%	Beta	From Davis *et al.*[4]
Two-stage screen sensitivity and specificity	Sensitivity 84.2% Specificity 90.7%	Sensitivity 75.8% Specificity 91.6%	Sensitivity 92.6% Specificity 89.8%	Beta	From Davis *et al.*[4]
Accept offer of hearing aid	66%	46%	86%	Beta	From Davis *et al.*[4,12] and Wilson *et al.*[17]
Utility gain from hearing aid	0.068	0.035	0.105	Beta	From Barton *et al.*[18] and Davis *et al.*[4]
Probability of using hearing aid in first 5 years	90%	80%	100%	Beta	From Davis *et al.*[12]
Probability of using hearing aid beyond first 5 years—screen cases	62%	46%	77%	Beta	From Davis *et al.*[4]
Probability of using hearing aid beyond first 5 years—GP-referral cases	81%	49%	97%	Beta	From Davis *et al.*[4]
Cost of one-stage screen	£8	£4	£12	Gamma left	Assumed those who use hearing aid beyond the first 5-years continue for the rest of their life
Cost of two-stage screen	£13	£7	£20	Gamma left	From Davis *et al.*[4]
Accept two hearing aids—screen cases	95%	75%	100%	Beta	From Stephens *et al.*[3] and Davis *et al.*[4]
Accept two hearing aids—GP-referral cases	80%	60%	100%	Beta	
Cost of single hearing aid and ear mould	£122	£98	£146	Gamma left	Taken from UK NHS 2009/10 Adult Hearing Services Indicative Tariff
Cost of audiological assessment	£57	£46	£68	Gamma left	
Cost of hearing aid fitting appointment	£69	£55	£83	Gamma left	
Cost of follow-up appointment	£49	£39	£59	Gamma left	
Cost of hearing aid repair	£26	£21	£31	Gamma left	
Mortality		Varies with age		N/A	Taken from Government Actuary's Department. Interim Life Tables, 2004–2006

Source: Morris and al., 2012

On the basis of these assumptions and results, the screening strategy appears to be very efficient: the following map illustrates the acceptability of this strategy from a financing point of view. Usually, the NICE (*National Institute of Clinical Excellence*) determines a willingness to pay threshold ranging from £20,000 to £30,000 for each year of good health gained. It can be seen that the probability of being below such a threshold is close to 1 (map 2).

Graph 1 – Acceptability curve of one-step screening strategy vs comparator in Morris et al.



Source: Morris and al. (2012)

We should note that these results probably have underestimated intangible costs (or quality of life score) related to hearing loss consequences on other health state dimensions, since the analysis relied on QALYs gained in the case of screening and earlier hearing aid access for people who did not have severe impairment. In this study, the quality of life gain was estimated to range between 0.035 and 0.105. However, these values are useful for the next analysis, where our reference values for quality of life gains are close. Moreover, it should be underlined that prices of hearing aids are very low: this limit is mentioned by the authors, who specified that the follow-up cost was probably underestimated. Hearing aids delivered at this price are basic ones[81].

2.2.2 Economic impact of hearing loss in France: scenarios and approximations

The literature survey of Shield (2006) conducted ten years ago allowed us to measure the expected impact of hearing aids on quality of life, particularly the psycho-social dimensions, at a time when technical devices were not as performant as today, even if this measure was not quantified in a robust way:

- Greater self confidence, self image and better communicative function resulting in overall higher self esteem, although these results are less obvious for older people;
- Less degradation of psychological health;
- Less functional difficulties for the elderly in the first three months of use;
- Improvements in psycho-social health perceptible in better quality of life scores after a couple of weeks;
- Less depression related to hearing loss;
- Improvements in social and familial activity;

[81] Cf. www.fdp.org.uk for an idea of the different choices and prices (refunded or not), depending on the nature of access to hearing aids: public sector (NHS) or private sector (£300 to £2500 per ear). For an idea of the price range in the private sector, see http://www.specsavers.co.uk/hearing/hearing-aids/hearing-aid-range. Internet sites consulted in March 2016.

- Increasing relationship between satisfaction related to hearing aids and hearing loss severity: the greater the severity of the hearing loss, is the greater the satisfaction (apart from very severe cases);
- Level of satisfaction independent of age;
- Less social isolation;
- Less feelings of stigmatisation for hearing aid users than for non users;
- Better emotional life.

Hearing aid users bear their impairment more easily than non-users (who are more often in denial) and are more aware of security. Their families estimate that wearers of hearing aids have improved cognitive capacities in comparison to non-users, and wearers are less introverted. Hearing aid users have in a better overall health state, particularly for relationships, self esteem, mental health and this is especially true for more severe hearing impaired people. This body of evidence – highlighted on the basis of Shield's scientific literature survey released before 2006 - seems to be reinforced by our previous literature survey of 2005-2015 in which statistical investigations have also supported the favourable impact of hearing aids on health state.

The consequences of hearing loss on all dimensions of health status, impose the use of a quality of life framework. However, for lack of reliable data on health referenced scores, we propose a few scenarios and approximations in order to assess the potential economic impact of hearing loss in France.

Investigating socio-economic costs related to hearing loss ('economic burden'), Shield (2006), the London economics/RNID (2010) and Archbold (2014) propose methods that we combine according to available data for France. Ideally, the main objective would be to estimate:

- Avoidable health, social and long-term direct direct costs related to hearing loss;
- indirect costs (loss of productivity, selection in the labour market, impact of noisy professional backgrounds…);
- a direct assessment of utility score benefits, or an indirect assessment of intangible costs – greater ones – estimated by the quality of life degradation with or without hearing aids. Intangible costs are estimated on the whole, by combining average quality of life scores and statistical values of human life, but these methods remain controversial.

In our approach, it is obvious that a precise analysis of each line is not possible. The estimation that will be proposed is therefore partial – not including all the costs and not assessing the utility scores – and approximate (relying on a certain number of assumptions). It consists of a rough estimate, to be compared to other available estimations in the literature. The first step of this economic reckoning is to give a possible value for intangible costs.

2.2.2.1 Quality of life, preference-based scores, QALYs and statistical value of a human life: a framework

In heath economics, cost-utility analysis consists of comparing at least two strategies regarding their costs (direct medical, direct non medical, indirect) and their consequences in terms of quality of life. Quality of life is estimated through validated scales; in France, the HAS

suggests using either the EQ-5D-3L (Euroqol) or the HUI3 (Health utilities index mark 3)[82]. Quality of life scores are obtained through a patient questionnaire and a scoring formula. Average scores – in general – can be reported on 0-1 scale (0= state equivalent to death and 1=state equivalent to perfect health) which, when combined with the length of life in this state, allow us to convert years of life in this state into healthy years of life, with the help of QALYs[83].

When there are two strategies for which costs and utility scores are assessed, it is possible to compute the incremental cost-utility ratio by comparing cost variation to utility variation: we thus obtain the cost to pay for one year in a perfect state of health. The issue is then to question if this cost is affordable from a social point of view or not. It depends on the collective willingness to pay.

The threshold for such a willingness to pay for one year in perfect health is not revealed in France by the HAS. However, it is known for the United Kingdom, and this threshold ranges between £20,000 and £30 000, i.e. in euros €25,840 and €38,760. This threshold reveals the upper collective willingness to pay for a year in perfect health and has indeed a connection with the statistical value of a human life. Although this range represents the lower value class for an extra QALY (Shiroawa et al., 2010), we propose to take as a reference €40,000[84]. We draw the reader's attention to the methodological precautions with this assumption, requiring us to to deduce the value of statistical life (VSL) from the threshold of willingness to pay for one additional QALY gained (and so on the value of one year of human life VHL) (Commissariat général de la stratégie et de la prospective, 2013). As stated, the main objective is to propose a framework and our assessment is based on short periods of time (without taking account of value of human life related to age). Moreover, we use the assessment method found in the literature, in order to compare rough values for lack of possibility to set up a cost-effectiveness analysis.

Economic evaluations abound for cochlear implants, for which it is possible to compare two strategies (implants vs traditional care) and to infer an incremental cost-effectiveness ratio (cost variation/utility variation). However, it is trickier to find in the literature a reference scale for average utility scores related to each age group and each level of hearing loss severity, especially as these scores themselves depend on the assessment tool (EQ-5D, HUI3…). Therefore, several reference values have been taken as references from the study of quality

---

[82] Cf. www.euroqol.org and www.healthutilitiesindex.com

[83] Example : if the loss in utility associated with a profound hearing loss were estimated to -0.46 over 10 years, the person would get a score of 0.54 for health state, so it can be deduced that this health state would represent 5.4 QALYs instead of 10 QALYs if he/she were in perfect health (in other words, the degradation of health state has resulted in a loss of 4.6 years in perfect health). If hearing aid equipment allowed the person a reduction in utility loss with a score of 0.74 (loss: -0.26) then the person would get a health state estimated to be at 7.4 QALYs for 10 years of life, meaning a gain of 2 QALYs thanks to hearing aids. In fact, this assessment should take into account the discount rate (time preference) but it won't be necessary to apply it in our estimation as far as it relies on the economic burden in 2014 (one year). This is very complicated

[84] The authors estimated for example the Australian threshold to be at €43,112, the American threshold to be at €56,374, but these thresholds would be several million euros in Asian countries. Shield (2006) has taken on the value of €44,000, as defined by the European commission for the Environment in 2003.

of life led by Shield (2006)[85], who has proposed a frame of reference for the European population (table 29).

Table 29 – Frame of reference for utility scores in hearing loss

Hearing loss severity	Moderate	Severe	Very severe or total
Average score for an adult person in good health	0.85	0.85	0.85
Average score associated with hearing loss	0.85	0.7	0.6
Score loss due to hearing impairment	0.05	0.15	0.25
Value for one QALY=40000€	2000	6000	10000

Source: Authors on basis of Shield (2006) and applying a 40,000 € value for one additional QALY gained

More than the absolute value of scores, these score variations are meaningful here. For example, if we were applying the HUI3 questionnaire which includes a direct question related to hearing dimension:

- A person would have a score of 0.788 if he/she has declared no limitation other than:
  - "able to hear what is said in a conversation with another person in a quiet room with a hearing aid, and able to hear what is said in a group conversation with at least three other people with a hearing aid";
  - "somewhat happy".

- As for the EQ-5D-3L questionnaire, a decrease in the score would happen for these illustrative cases:
  - A person who has "some problems with performing usual activities" would have a loss in their score of 0.117 (if no other limitation);
  - A person who declares "moderate pain or discomfort" would have a loss in score of 0.204 (if no other limitation);
  - A person who cumulates these two limitations would have a loss in score of 0.24 (if no other limitation);

2.2.2.2 Annual cost of hearing loss (2014) according to the quality of life perspective

Starting from the data collected in the first section as well as analyses related to economic burden and quality of life, we propose an estimation of the economic cost of non-equipped hearing loss.

The components of costs are tricky to evaluate since we do not know direct medical and non-medical costs, including costs relating to the social domain, nor do we know the indirect costs

[85] The second estimation method consists of an assessment of lost revenues because of hearing loss. This method seems to be less advisable to the extent that a large proportion of hearing impaired people are older and also because this human capital approach is less used. Moreover, the quality of life approach presents the advantage of covering all the dimensions, including occupational ones (particularly in HUI3 questionnaire).

(loss of productivity). As concerns the economic burden of illness, we estimate it by quality of life method.

This method requires definition of the following variables:

- The French adult population affected by hearing loss according to the different levels of severity;
- The French adult population who are not hearing aid equipped and who should be (eligible population but not owning hearing aids);
- The French adult population being equipped but not using its hearing aids;
- The quality of life associated with the different levels of severity;
- The monetary value associated with a healthy year of life.

The survey Handicap-Santé 2008 presented charts of hearing loss prevalence according to of severity levels, but without releasing the precise occurrences. As we do not know these values by age groups, we have retained those of the 1998 survey in order to estimate hearing loss prevalence for the adult population in 2014 according to severity levels (remember that these data have remained steady over time, as shown in the first section):

Table 30 – Reference rates for hearing loss prevalence according to severity levels

Prevalence rate/1000 people	Slight to moderate	Moderate to severe	Very severe to total
<20	12.3	0.7	1.3
20-39	18.3	2.7	1
40-59	51.5	17.6	2.8
60-74	157	56.6	8.8
75 and over	229.6	158.7	37.3
Overall	**50.4**	**24.6**	**5.2**

Source: Survey Handicap santé 1998

On the basis of demographic data for the year 2014 (database Eco-santé OCDE), we deduce headcounts by age groups in mainland 'metropolitan' France and for all French possessions ('the whole of' France) (table 31).

Table 31 – Estimation of French adult population in 2014 affected by disabling hearing loss (moderate to total AFL following the definition of the DREES 2014)

AFL severity				Stat. Eco santé year 2014	Stat. Eco-santé year 2014	Metropolitan France 2014 - Number of people			Overall France 2014 - Number of people		
Group age	Moderate	Severe	Very severe to total	Metrop. France	Overall France	Moderate AFL	Severe AFL	Very severe to total AFL	Moderate AFL	Severe AFL	Very severe to total AFL
20 à 39 ans	1.83%	1,0%	0.1%	15 551 014	16 001 614	284 584	155 510	15 551	292 830	160 016	16 002
40 à 59 ans	5.15%	1.76%	0.28%	17 180 853	17 709 879	884 814	302 383	48 106	912 059	311 694	49 588
60 à 74 ans	15.7%	5.66%	0.88%	9 720 665	9 941 571	1 526 144	550 190	85 542	1 560 827	562 693	87 486
75 ans ou plus	22.96%	15.87%	3.73%	5 875 312	5 976 043	1 348 972	932 412	219 149	1 372 099	948 398	222 906

Source: Authors, data pop. Eco-Santé 2016, data prevalence HS1998

As mentioned above, and by hypothesis, the average health score for an adult in Europe is 0.85 and:

- A moderate hearing loss leads to a 0.05 loss in utility (score of 0.8);
- A severe hearing loss leads to a 0.15 loss in utility (score of 0.7);
- And a very severe hearing loss leads to a 0.15 loss in utility (score of 0.6).

The monetary value for a healthy year is fixed at 40,000 euros.

If hearing impaired people in France couldn't access any hearing aid equipment in order to compensate for their impairment (i.e. if nobody were equipped), intangible costs associated to AFL would amount to 23.3 billion euros in metropolitan France and 24 billion euros for the whole of France (table 32).

Table 32 – Economic burden of hearing loss under assumption of no hearing aid equipment access.

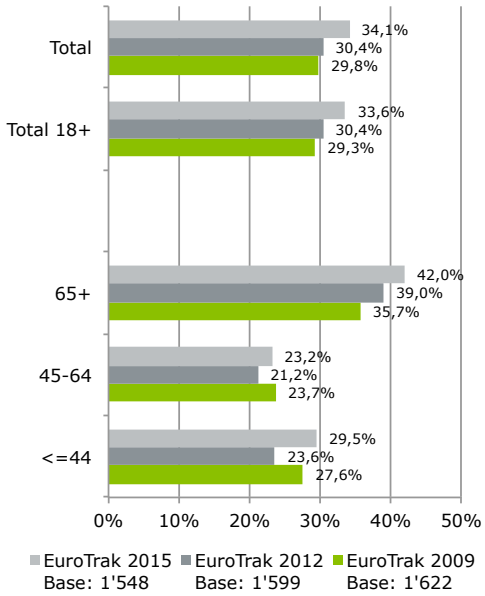
Hypothesis : no hearing aid equipment at all in France				
Severity	**Moderate AFL**	**Severe AFL**	**Very severe to total AFL**	**Overall**
Metrop. France	4 044 514	1 940 495	368 348	6 353 357
Overall France	4 137 814	1 982 801	375 982	6 496 597
Cost Metrop. France	8 089 027 052 €	11 642 968 837 €	3 683 483 920 €	23 415 479 809 €
Cost Overall France	8 275 628 849 €	11 896 805 719 €	3 759 815 039 €	23 932 249 607 €

Source: Authors.

As a comparison, for Europe in 2006, and with a reference value of €44,000, the economic burden of hearing loss rose to €284 billion (Shield, 2006). If we don't include the value of Swedish willingness to pay (€70,000), the economic burden would amount to 41 billion euros.

It is now possible to estimate the costs saved by access to hearings in France. In order to start this estimation, let's assume that equipped persons do not recover a health state similar to those without hearing loss, but recover 75% of the degraded quality of life. This assumption should be linked to the appraised satisfaction through qualitative surveys (for example, Eurotrak 2015) and the literature survey. Let's also assume that the data for people being equipped at every adult age group in the Eurotrak survey 2015 are reliable (these data were convergent with those of French surveys). These frequencies are represented in graph 8.

Graph 8 – Hearing aid access by age groups



Source: Eurotrak, 2015

Group ages only partially match with those of table 32. Moreover, we have applied the rate of 29.5% to the age group {20-39} ; the rate of 23.2% to the age group {40-59} ; and the rate

of 42% to the older groups. Table 33 shows the gain obtained from actual hearing aid equipment, which would allow 6.6 billion euros of intangible costs to be saved: this is the monetary value associated to additional quality of life gained. Intangible costs amount to 16.7 billion euros: this is the loss in quality of life related to hearing loss. In this table, the line 'people not being equipped with HA' includes not only the population eligible for hearing aids but not owning them but also the non eligible population for hearing aids (50% of hearing impaired people).

Table 33 – Intangible cost saved by hearing aid access

Actual cost savings related to equipment in France (Hypothesis : hearing aid users gain 3/4 utility score)				
Severity	**Moderate AFL**	**Severe AFL**	**Very severe to total AFL**	**Overall**
Metrop. France	4 044 514	1 940 495	368 348	6 353 357
Not equipped people	2 547 736	1 201 774	224 630	3 974 140
Cost Metrop. France	5 843 860 475 €	8 318 724 136 €	2 605 595 568 €	16 768 180 180 €
Cost savings	2 245 166 576 €	3 324 244 701 €	1 077 888 352 €	6 647 299 629 €

Source: Authors.

If France had reached the target rate of 50% of hearing impaired people owning hearing aids (as in the case of Denmark which covers the optimal rate of people), intangible costs saved would be 8.7 billion euros (table 34). and intangible costs would amount to 14 billion euros. This means that cost savings of 2.1 billion euros could be gained by a revision of access rules to hearing aids in order to reach the target of 50% (in the table, by definition, the number of non equipped people is equivalent to half the hearing impaired people).

Table 34 – Avoidable intangible costs by an improvement in hearing aid access

Target for cost savings (Hypothesis : all egilible people is equipped)				
Severity	**Moderate AFL**	**Severe AFL**	**Very severe to total AFL**	**Overall**
Metrop. France	4 044 514	1 940 495	368 348	6 353 357
Not equipped people	2 022 257	970 247	184 174	3 176 678
Cost Metrop. France	5 055 641 907 €	7 276 855 523 €	2 302 177 450 €	14 634 674 881 €
Cost savings	3 033 385 144 €	4 366 113 314 €	1 381 306 470 €	8 780 804 928 €
Avoidable cost / target 50%	-788 218 568 €	-1 041 868 613 €	-303 418 118 €	-2 133 505 299 €

Source: Authors.

However, another issue to consider is compliance. We saw in the first section that France, together with Switzerland, presented the best performance in the Eurotrak 2015 survey, with a low rate rate of owners who were non-users (10%), with non-use defined as the number of people owning hearing aids but not using them (never or for less than one hour a day). If compliance were complete, this would reduce intangible costs of 665 million euros. This relatively low gain indicates the performance of France for compliance and it might be considered as a cost which cannot be reduced.

Table 35 – Avoidable intangible costs by an improvement in compliance

Target for compliance (Hypothesis : all HAs owners are users)				
Severity	**Moderate AFL**	**Severe AFL**	**Very severe to total AFL**	**Overall**
Metrop. France	4 044 514	1 940 495	368 348	6 353 357
Not equipped people	2 697 414	1 275 646	239 002	4 212 061
Cost Metrop. France	6 068 377 133 €	8 651 148 606 €	2 713 384 404 €	17 432 910 143 €
Cost savings	2 020 649 919 €	2 991 820 231 €	970 099 516 €	5 982 569 666 €
Avoidable cost / perfect compliance	-224 516 658 €	-332 424 470 €	-107 788 835 €	-664 729 963 €

Source: Authors.

Hence, this cost reduction target relying on compliance improvement seems to be difficult to meet since the French performance is in itself a reference point compared to some other countries (Norway, Denmark, the United Kingdom). Conversely, let us study the intangible costs saved in France due to its better compliance in comparison to these countries. For example, if we take the Danish rate there are 20% of non complying patients:

Table 36 – Avoided intangible costs in France in comparison to the Danish compliance rate

Cost savings regading the Danish rate for compliance				
Severity	**Moderate AFL**	**Severe AFL**	**Very severe to total AFL**	**Overall**
Metrop. France	4 044 514	1 940 495	368 348	6 353 357
Not equipped people with Danish values (including compliance)	2 426 708	1 164 297	221 009	3 812 014
Cost Metrop. France	5 662 318 936 €	8 150 078 186 €	2 578 438 744 €	16 390 835 866 €
Cost savings / initial situation	2 426 708 116 €	3 492 890 651 €	1 105 045 176 €	7 024 643 943 €
Cost savings regarding the Danish compliance	-406 058 197 €	-501 070 420 €	-134 945 660 €	-1 042 074 277 €

Source: Authors.

If in France 20% of patients were non- compliant (instead of 10%), intangible costs (or value of the loss of quality of life) would be increased by 1 billion euros. This statement has to be placed in perspective against the analysis of health system organisation: free delivery, as in Denmark, allows almost total coverage for the people eligible for equipment. However, the weaker patient follow-up associated with this free delivery in NHS systems leads to a loss in effectiveness, which translates into a 'loss' of hearing aid users, and so into in additional intangible costs.

Therefore, it is necessary to simultaneously support hearing aid access, to give strong incentives to audiologists to improve the quality of follow-up services and to give strong incentives for patients to use these follow-up services.

2.2.2.3 Additional health care costs due to non-equipped hearing loss and efficiency of hearing aids regarding eligible population: approximations

The previous scenario was an exercise which permitted the estimation of the impact of hearing aid access and compliance on additional quality of life gain, as valued in monetary terms. It is also interesting to design an assessment scenario in order to estimate the size of hearing aid costs, of saving costs related to equipment and of quality of life benefits. Once again, we propose a simulation exercise relying on some assumptions:

- The total number of people affected by hearing loss (moderate, severe and very severe AFL) in 2014 is assessable on the basis of prevalence rates by age groups in the survey 'Handicap-Santé 1998' (table 30) and on the estimated demographic population in metropolitan France in 2014 (Eco-santé OCDE);

- The number of this hearing impaired population not accessing hearing aids is available in the Eurotrak 2015 survey, as well as the compliance rate (10% of hearing aid owners are not users);

- The degradation of quality of life according to impairment severity levels is assessable on the basis of Shield's references (2006), since they seem to be reliable regarding the recent literature (table 29);

- Hearing impaired people eligible for hearing aids but who are not equipped is related to an additional cost in terms of health care consumption, because of the morbidity linked to hearing loss. We assume that this additional annual cost depends on the AFL severity and we retain as monetary values: +400 euros/moderate AFL, +1,200 euros/severe AFL and +2,000 euros/very severe AFL. These estimations are very debatable, but they rely on the IRDES study (Sirven and Bougueil, 2016) which estimated that the additional health care cost for frail people amounted to 2,000 euros a person/year. Moreover, the previous survey (see Foley, 2014) showed an increase in health care expenditure for hearing impaired people ranging around +39% in contrast to the same population without hearing loss: in France, the average health care expenditure per capita amounts to 3,000 euros beyond age of 55, therefore an average add-on of 1,000 euros relating to severe hearing loss seems to be reliable. Assuming that this monetary add-on is associated with the higher loss in quality of life score (0.25), we can see the values for a 0.15 loss of utility (1,200 euros) and for a 0.05 loss of utility (400 euros). This linearity in costs is also debatable. Nevertheless, taking into account the previously underlined elements concerning hearing loss morbidity effects, this seems an appropriate estimate;

- We assume that the complying hearing aid users have a lower loss in utility (this loss is reduced by 75% because of satisfaction linked to hearing aids), but as they do not return to the same health state as the same people without hearing loss, we assume that additional annual health care costs are, following the AFL severity levels: 100 euros; 300 euros; 500 euros (as a proportional reduction of health care costs of 75% in relation to hearing impaired people who are not equipped);

- We estimate the additional cost of hearing aid access and the saving cost according to population types (HAs owners and users/ HAs not owners or HAs owners not users) and according to hearing loss severity for the French population if the equipment target of 50% was reached (that is the whole eligible population);

- The additional cost savings *relying on optimal access* are then estimated on the basis of these values, taking into account non-compliance (which is considered to be non-improvable). This cost is estimated for 6 years (the median life span of a piece of equipment). This is then the additional health care cost born by society, and is attributable to the lack of hearing aid access for the eligible population.

Thus, under these assumptions, the health care cost savings amounts to around 290 million euros for 2014, that is, for 6 years and in constant euros without discounting, 1.7 billion euros. This is the morbidity cost related to disabling hearing loss that could be saved by all the financing contributors (National health Insurance, complementary health insurances and patients) if an optimal access for hearing aids were implemented for eligible people (50% of the whole hearing impaired population), taking into account a non-modifiable loss of effectiveness related to a compliance rate of 10% (hearing aid owners but non-users).

Next, the number of people to equip (including both compliant and non-compliant groups as it is not possible to distinguish between them for hearing aid access) is estimated in relation to the target. We assess the cost of hearing aid equipment for this eligible population (797,461 people). On the basis of our reference values – the unit cost for a hearing aid (€1,535), average cost of an initial ENT consultation (€50) and annual battery cost (€50/year), we can estimate the total cost of hearing aid equipment for this additional population for 6 years (median lifespan of equipment). This equipment cost would amount to 1.5 billion euros over 6 years. Yet, this additional equipment cost would allow us to avoid over the same time (6 years) 1.7 billion euros in terms of health care expenditure (taking into account compliance), that is, a saving of 200 million euros.

Finally, we estimate the quality of life benefits for this fraction of people who were newly equipped during the 6 years of equipment, taking into account compliance rate and the partial recovery of quality of life for people both equipped and compliant. This utility gain would range around 48,000 QALYs for 685,817 people.

Under all these assumptions:

- The total cost of equipment for eligible hearing impaired persons (compliant or not), estimated to be 1.5 billion euros and linked to a benefit of 48,000 QALYs (for compliant users), leads to an incremental cost-effectiveness ratio of €5,462/QALY. It means that a cost of €5,219€ gains one healthy year, which is a ratio largely below the previous thresholds of willingness to pay. Even if the gain in quality of life were markedly lower (for example, 5 times lower), this ratio would deserve be considered as a trade-off regarding these thresholds (€26000/QALY);

- If we compare the net differential cost (additional cost of equipment minus health care cost savings), the incremental cost-effectiveness ratio (ICER) would be equal to -

€830/QALY: in other words, the target strategy of 'all eligible people are equipped' saves costs and provides an increased quality of life, and is thus the dominant strategy.

Under which assumptions would the target strategy of 'all eligible people are equipped' be rejected? It would be the case if either the increase in QALYs gained was 5 times less than in this case study (that is an unlikely situation given the literature on the association between hearing loss and morbidity and regarding the low score variations of utility employed in the case study), or if the additional costs related to hearing loss (in terms of health care expenditure impact) were much lower:

- If we halve the health care cost reference values for all severity levels (that is €200; €600; €1,000 for people being not equipped and €25; €75; €125 for people being equipped) the ICER would amount to €9,759/QALY.
- The ICER would amount to €9,085/QALY with the cost reference values of €0; €600; 1,000€ for people being not equipped and €0; €150; €250 for people being equipped).

Even under relaxed assumptions about the health care costs for a hearing impaired person not being a hearing aid owner, the ICER remains socially acceptable.

Beyond assumptions relating to this simulation exercise, it should be noted that we have not provided an estimation for indirect costs (for example, the impact of hearing loss on productivity) or social costs linked to dependency. These dimensions would raise the total cost savings.

This entire case study, which relies on acceptable assumptions, underlines the requirement for a substantial economic assessment that would corroborate these results, that is the highly efficient target strategy that 'all eligible hearing impaired people are equipped'.

However, it remains to solve the touchy question of hearing aid financing likely to support access to them, and especially the question of the relative financial contributions of payers, as seen in the first section of the report. Moreover, if the National Health Insurance could greatly increase its financial role in hearing aid reimbursement, we would anticipate a bounce effect for people being equipped but having postponed hearing aid renewing. This effect would inevitably increase the budget impact of hearing aid access.

Table 37 – Scenario for an economic assessment of the strategy 'all eligible hearing impaired people are equipped'

Scenario for an ICUR assessment of the target strategy (50% equipment) including compliance rate - 6 years (without discounting) - Adult people					
Severity	References	Moderate AFL	Severe AFL	Very severe to total AFL	Overall
Population / Metropolitan France	AFL prevalence/age groupsSelon prévalence LFA par âge	4 044 514	1 940 495	368 348	6 353 357
Not equipped people (eligible and not eligible) and HA owners not users	Equipment rate (Eurotrak 2015) and compliance rate	2 697 414	1 275 646	239 002	4 212 061
Medical costs / year for people not being equipped or owners not users	hyp : €400 moderate AFL - €1200 severe AFL - €2000 very severe AFL	1 078 965 432 €	1 530 775 039 €	478 003 580 €	3 087 744 051 €
Medical costs / year for HA owners users	hyp : €100 moderate AFL - €300 severe AFL - €500 very severe AFL	134 709 995 €	199 454 682 €	64 673 301 €	398 837 978 €
Medical costs / year if equipement target 50% and compliance rate 90%	hyp : €400 moderate AFL - €1200 severe AFL - €2000 very severe AFL	922 149 084 €	1 327 298 447 €	419 917 167 €	2 669 364 698 €
Medical costs for HA owners users if target 50% and compliance rate 90%	hyp : €100€ moderate AFL - €300 severe AFL - €500 very severe AFL	182 003 109 €	261 966 799 €	82 878 388 €	526 848 296 €
Cost savings with an optimal access for one year (taking into account compliance rate 90%)	Addtional cost / target	109 523 234 €	140 964 475 €	39 881 326 €	290 369 035 €
Hearing aid equipment - expected cost	unit price €1 535 * 597 543 sold devices in 2014 (snitem)				917 228 505 €
Equipped people with HA	Population in France in 2014	1 496 778	738 721	143 718	2 379 217
Number of purchasers	Population in France in 2014 (70% binaural)				351 496
Eligible people not being equipped	Population in France if target 50% (including compliance rate)	525 479	231 526	40 456	797 461
Cost savings for 6 years of equipment	6 years : median lifespan of a device (Eurotrak 2015)				1 742 214 208 €
Additional cost to afford in order to reach the target	unit price : €1535				1 224 102 870 €
Batteries cost for 6 years	€50/year				239 238 346 €
Initial ENT consultation	50 €				39 873 058 €
Total cost for a 6-years equipment					1 503 214 273 €
Net cost (additional equipment cost - medical cost savings)					-238 999 935 €
Recall : equipped and compliant number of people	Expected population in 2014	1 347 100	664 849	129 347	2 141 295
Eligible people who will be compliant		472 931	208 374	36 410	717 715
QALYs gained for one year	Hyp : the decrease in utility score is reduced of 75%	17 735	23 442	6 827	48 004
QALYs gaines for 6 years	Median lifespan of a device	106 410	140 652	40 961	288 023
Equipment : incremental cost-utility ratio					5 219 €
All costs included : incremental cost-utility ratio					-830 €

3 Conclusion

This overview of hearing loss and hearing aid access in France emphasizes four main lessons, in the light of international comparisons and of medical scientific literature:

1) Disabling hearing loss (or moderate to total auditive functional limitations), by reducing the person's communication capacities, rebounds significantly on broader dimensions of health state (mobility, autonomy, daily activities, pain/discomfort, anxiety/depression) through a succession of chain reactions, the main ones being *social isolation, cognitive decline, suffering at work, mental troubles and falls*. Hearing loss represents a major impairment which, by affecting more than six million French (often older) people, not only has deleterious effects on quality of life but also leads to additional health and social care expenditures for society as a whole;

2) The health policy for secondary prevention, that could consist of screening and equipping hearing impaired people with hearing aids, is non-existent regarding public reimbursement. National Health Insurance, by covering only 8% of the hearing aid price for adults, has almost excluded hearing loss from its management policy for health risk, leaving the out-of-pocket payment to complementary insurance bodies and above all to patients. *In fine*, families, close relatives and the whole society bear the costs of this impairment, as well as for the loss of autonomy since one third of the eligible population for hearing aids don't get them. Moreover, inequalities relating to the rights of those insured with complementary health bodies, their revenue and ability to pay for equipment contribute to maintain these social inequalities in health, by the renouncement effect.

3) As concerning payment schemes for audiologists, reflection must take place as their effectiveness. In order to regulate the hearing aid sector and to design an incentive payment for hearing aids, a trade-off is necessary between the objectives of expenditure control, health care quality and freedom of choice; this must take place in a hypothetic framework which assumes a higher coverage of hearing aids. There are many tools which would allow us to find the optimal trade-off for public financing, but *we must be very cautious about the issue of a possible decoupling of the device and the service*. This decoupling model brings up adverse effects which are similar to those of 'cost-plus' payment, leading to increasing prices and putting patients' compliance at stake, that is the therapeutic efficiency of hearing aids for some patients. At the same time, recourse to prospective payment systems is increasingly implemented for pricing in health systems, and as a growing attention is paid to patients' empowerment, this concept of divisibility of device/service falls into an old-fashioned economic approach in terms of optimal incentives. International comparisons highlight the impact of coverage and health care organisation on hearing aid access, equipment renewal and patients' compliance.

4) The imperative revision of coverage rules for hearing aids in France has to take into account not only the incentives of payment schemes for audiologists, but also cost-effectiveness studies which shed light on the evidence regarding expected service of

hearing aids. By intuition, this expected service is at least 'important', even extremely so:

- Adult hearing aid owners – that is two thirds of the eligible population for equipment – by paying out of their own pocket 950 euros (one ear) to 1,900 euros (two ears), purchase the equipment despite the financial charge, which indicates the nature of the benefit (fundamental one);
- The medical scientific literature unambiguously reports the negative waterfall effects of hearing loss, but also show the beneficial effects of hearing aid access (at least on cognitive decline and mental health, since the systematic reviews on this topic are expected for 2016);
- The simulation exercise of the cost-utility ratio that has been proposed in this report, although relying on simplistic assumptions, gives some approximate values that lead one to believe in the efficiency hearing aid strategy, and even in a dominant hearing aid strategy for society as a whole.

These four main lessons lead to some proposals for the regulation of the hearing aid sector in France:

- ***To reinforce public authorities' information at all decision making levels of the health system on the burden of hearing loss:***
  - on the basis of a systematic review of the medical and economic scientific literature;
  - through prospective cost-efficiency assessments, by collecting useful data in sequential or regular surveys based on the working and older population, in order to infer the differential cost-utility ratio between strategies;
  - by estimating the budget impact of hearing aid equipment depending on several coverage scenarios from the National Health Insurance's point of view.

- ***Before health care demand:***
  - inform the whole population on the consequences of noise exposure and presbycusis;
  - to reform access rights for hearing aids independently of status considerations (illness, impairment, old age) in order to set up a level playing field for hearing impaired people in France.

- ***Following health care demand:***
  - To ensure a sufficient coverage of needs with a refunding of cheaper equipment, on the basis of a prospective fixed price and a minimum length of use, and let willing patients pay for their own free choice in the face of differentiated devices, following the principle of the responsibly fixed tariff applied to drugs in France;
  - To inform people who need equipment about the expected service for the different types of hearing aids, by disassociating common and recognised qualities in auditive rehabilitation from comfort options;
  - To assess, from the National Health Insurance point of view, the budget impact related to reimbursement rules revision, including not only eligible people who

are not hearing aid owners but also remediation behaviour for people equipped for more than six years.

- ***Before health care supply:***
  - To link, using appropriate incentives, networks of general practitioners and occupational health doctors in a secondary prevention campaign in real-time, during medical consultations of people at the end of their active life, aged 60-65. This screening could be carried out with little costs on the basis of a short questionnaire comprising two questions that allow easy identification of hearing loss occurrence.

- ***Following health care supply:***
  - To maintain the principle of a prospective payment – for which the incentive properties are well-known – for audiologists, in order to promote both expenditure control and health care quality, then to promote the compliance and therapeutic efficacy of hearing aids for all patients, whatever their capability to pay.

These overall suggestions have found their justification in the analytical survey of the recent literature presented in this report. They impose the need for an urgent examination of the regulatory rules for the hearing aid sector in France, at a moment where ageing, and listening to amplified music among the young risks contributing to aggravated hearing loss prevalence in France.

References

Acar B, Yurekli MF, Babademez MA, Karabulut H, Karasen RM. Effects of hearing aids on cognitive functions and depressive signs in elderly people. Arch Gerontol Geriatr. 2011 May-Jun;52(3):250-2

Archbold Sue, Lamb Brian, O'Neill Ciaran, Atkins John. The real cost of adult hearing loss: reducing its impact by increasing access to the latest hearing technologies, The ear foundation. 2014. 24 p.

Alcimed-Direction de la sécurité sociale. Analyse économique du secteur des appareillages optiques et auditifs. Rapport final. 2011. Mars. 121 p.

Alcimed-CNSA. Etude européenne sur le marché des aides techniques destinées aux personnes handicapées et âgées en perte d'autonomie. Synthèse transversale et annexe aides auditives. 2009. Décembre.

Amieva H, Ouvrard C, Giulioli C, Meillon C, Rullier L, et al. Self-Reported Hearing Loss, Hearing Aids, and Cognitive Decline in Elderly Adults: A 25-Year Study. J Am Geriatr Soc. 2015 Oct;63(10):2099-104.

Autorité de la Concurrence. Décision n°16-SOA-01 du 3 février 2016 relative à une saisine d'office pour avis portant sur le secteur des audiprothèses. 2016. Fév. 8 p.

Bainbridge KE, Hoffman HJ, Cowie CC. Diabetes and hearing impairment in the United States: audiometric evidence from the National Health and Nutrition Examination Survey, 1999 to 2004. Ann Intern Med. 2008;149:1–10.

Bernabei V, Morini V, Moretti F, Marchiori A, Ferrari B, et al. Vision and hearing impairments are associated with depressive--anxiety syndrome in Italian elderly. Aging Ment Health. 2011 May;15(4):467-74.

Commission d'évaluation des produits et prestations. Avis de la commission 01/04/2008 sur les dispositifs appareils électroniques correcteurs de surdité (titre II, chap.3 de la LPP mentionnés à l'article L. 165-1 du code de la sécurité sociale). 2008. Avril. 22 p.

Comité économique des produits de santé. Rapport d'activité 2014/2015. 2015. Septembre.

Commissariat général à la stratégie et à la prospective (Rapport Baumstark L, Dervaux B, treich N). Eléments pour une révision de la valeur de la vie humaine. Rapports et documents. Tome 2. 2013. Avril. 28 p.

Conseil économique, social et environnemental (Beaudet T, Couty E). La place des dispositifs médicaux dans la stratégie nationale de santé. 2015. Janvier. 66 p.

Cour des comptes. L'accès aux soins des ménages défavorisés : un bilan en demi-teinte, une action à mieux cibler (chapitre XII du rapport Sécurité sociale). 2015. Sept. pp.415-448.

Cour des comptes. Les dispositifs médicaux : une dépense non maîtrisée (chapitre X du rapport Sécurité sociale). 2014. Sept. pp.291-318.

Cour des comptes. La prise en charge par les organismes de protection sociale de l'optique correctrice et des audioprothèses (chapitre XIV du rapport Sécurité sociale). 2013. Sept. Pp. 393-420.

Conseil national de la consommation. Rapport du CNC relatif aux prothèses auditives. 2000. Mars. NOR : ECOC0000082X. Consultable en ligne.

Davis A, Smith P, Ferguson M, Stephens D, Gianopoulos I. Acceptability, benefit and costs of early screening for hearing disability: a study of potential screening tests and models. Health Technol Assess 2007;11(42).

Dawes P, Emsley R, Cruickshanks KJ, Moore DR, Fortnum H, et al. Hearing loss and cognition: the role of hearing AIDS, social isolation and depression. PLoS One. 2015;10(3)

Dranove D, Satterthwaite MA. The industrial organization of health care markets. Chp.20 in Handbook of health economics. Vol 1. Part B. ed. Elsevier. 2000. pp1093-1139.

Eco-Santé OCDE. Open database. http://www.ecosante.fr Values on February 2016.

EHIMA. Market surveys Eurotrak (2009, 2012, 2015). Available online http://www.ehima.com/documents/

Ferguson MA, Kitterick PT, Edmondson-Jones M, Hoare DJ Hearing aids for mild to moderate hearing loss in adults (Protocol). The cochrane collaboration. Ed. Wiley. 2015.

Fellinger J, Holzinger D, Gerich J, Goldberg D. Mental distress and quality of life in the hard of hearing. Acta Psychiatr Scand. 2007 Mar;115(3):243-5.

Fisher D, Li CM, Chiu MS, Themann CL, Petersen H, et al. Impairments in hearing and vision impact on mortality in older people: the AGES-Reykjavik Study. Age Ageing. 2014 Jan;43(1):69-76.

Foley DM, Frick KD, Lin FR. Association of Hearing Loss and Health Care Expenditures in Older Adults. Journal of the American Geriatrics Society. 2014;62(6):1188-1189.

Garnero M, Le Palud V (DREES). Les contrats les plus souscrits auprès des organismes complémentaires santé en 2010. Document de travail Série statistiques. N°191. 2014. Août. 78 p.

Genther DJ, Frick KD, Chen D, Betz J, Lin FR. Association of hearing loss with hospitalization and burden of disease in older adults. JAMA. 2013 Jun 12;309(22):2322-4

Genther DJ, Betz J, Pratt S, et al. Association of Hearing Impairment and Mortality in Older Adults. The Journals of Gerontology Series A: Biological Sciences and Medical Sciences. 2015;70(1):85-90.

Godinho L.. Analyse sectorielle du secteur de l'audioprothèse en France. Document de travail. 2015a. Décembre.

Godinho L. What is the most efficient reimbursement system in Europe ? A statistical look at the wide range of European hearing aid reimbursement systems. The Hearing Rewiew. 2015b. Dec. – Available online : http://www.hearingreview.com/2015/12/efficient-reimbursement-system-europe/

Grant-Salmon T. The European hearing aid market. Audio-infos. N°81. 2013. Sept. Pp.20-23.

Haeusler L, Mordier B. Vivre avec des difficultés d'audition – Répercussions sur les activités quotidiennes, l'insertion et la participation sociale. Dossiers solidarité et santé. 2014 fev ; n°52 :1-17.

Haeusler L, De Laval T, Millot C. Etude quantitative sur le handicap auditif à partir de l'enquête « Handicap-Santé ». Document de travail, série Etudes et recherches. 2014 août ; n°131 : 156 p.

Haut Conseil pour l'avenir de l'assurance maladie (HCAAM). Rapport annuel 2013. 2013a. 273 p.

Haut Conseil pour l'avenir de l'assurance maladie (HCAAM). La généralisation de la couverture complémentaire en santé. Rapport. 2013b. Juillet. 120 p.

Haut conseil pour l'avenir de l'assurance maladie (HCAAM). Note sur les dispositifs médicaux. 2008. Mai. 79 p.

Hung S C, Liao K F, Muo C H, Lai S W, Chang C W, Hung H C. Hearing los sis associated with risk of Alzheimer's disease : a case§control study in older people. J Epidemiol. 2015 May 16 ;25(8) :517-521.

Inserm (Institut national de la santé et de la recherche médicale). Activité physique et prévention des chutes chez les personnes âgées. Synthèse et recommandations. 2014. 114 p.

Inspection générale des affaires sociales (IGAS). Evaluation de la prise en charge des aides techniques pour les personnes âgées dépendantes et les personnes handicapées. Rapport (P. Blanchard, H. Strohl-Maffesoli, B. Vincent). 2013. Avril. 115 p.

Inspection générale des affaires sociales (IGAS). Evolution et maîtrise de la dépense des dispositifs médicaux. Rapport Tome 1 (A. Morel, A. Kiour, A. Garcia). 2010. Nov. 171 p.

InVS (Institut de veille sanitaire), Handicap auditif, limitations et déficiences fonctionnelles :

Principaux résultats de l'enquête Handicap-Santé 2008-2009, France. Bull Epidémiol Hebd. 2015;(42-43):796-8.

Le Monde daté du 29 Septembre 2009. Les Français malentendants tardent à s'équiper d'audioprothèses. Archive online in www.lemonde.fr.

Le Monde daté du 12 Mars 2000. De plus en plus performantes, les aides auditives sont très mal remboursées. Archive online in www.lemonde.fr.

Le Monde daté du 16 Mai 1996. Douze mille francs l'unité. Archive online in www.lemonde.fr.

Leusie S. Privation sensorielle auditive et réhabilitation chez le sujet âgé : conséquences sur le fonctionnement cognitif. Thèse de doctorat en neurosciences. Université Claude Bernard - Lyon I, 2015

Li C-M, Zhang X, Hoffman HJ, Cotch MF, Themann CL, Wilson MR. Hearing Impairment Associated With Depression in US Adults, National Health and Nutrition Examination Survey 2005–2010. JAMA otolaryngology-- head & neck surgery. 2014;140(4):293-302.

Lin FR, Metter EJ, O'Brien RJ, Resnick SM, Zonderman AB, et al. Hearing loss and incident dementia. Arch Neurol. 2011 Feb;68(2):214-20.

Lin FR, Ferrucci L, Metter EJ, An Y, Zonderman AB, et al. Hearing loss and cognition in the Baltimore Longitudinal Study of Aging. Neuropsychology. 2011 Nov;25(6):763-70

Lin FR, Ferrucci L. Hearing Loss and Falls Among Older Adults in the United States. Archives of internal medicine. 2012;172(4):369-371.

Lin FR, Yaffe K, Xia J, et al. Hearing loss and cognitive decline in older adults. JAMA Intern Med. 2013;173:293–299.

Lin FR, Ferrucci L, An Y, Goh JO, Doshi J, et al. Association of hearing impairment with brain volume changes in older adults. Neuroimage. 2014 Apr 15;90:84-92.

Liu CF, Collins MP, Souza PE, Yueh B. Long-term cost-effectiveness of screening strategies for hearing loss. J Rehabil Res Dev. 2011;48(3):235-43.

Ministère du travail, des relations sociales, de la famille, de la solidarité et de la ville – Secrétariat d'Etat chargé de la famille et de la solidarité. Plan 2010-2012 en faveur des personnes sourdes et malentendantes. 2010. Février.

Mener DJ, Betz J, Genther DJ, Chen D, Lin FR. Hearing Loss and Depression in Older Adults. Journal of the American Geriatrics Society. 2013;61(9):1627-1629.

Mougeot M, Naegelen F. Régulation et tarification des hôpitaux. Ed. economica. 2011.

Morris AE, Lutman ME, Cook AJ, Turner D. An economic evaluation of screening 60- to 70-year-old adults for hearing loss. J Pub Health. 2012 Sept 35 ;1 :139 :146.

OECD. Panorama de la santé 2013. 2015. Available online: http://www.oecd.org/fr/sante/systemes-sante/panorama-de-la-sante-19991320.htm Values in February 2016.

WHO. Deafness and hearing loss. Fact Sheet n°300. 2016. Mars. http://www.who.int/mediacentre/factsheets/fs300/en/ Values in March 2016.

Schmulian Taljaard D, Olaithe M, Brennan-Jones CG, Eikelboom RH, Bucks RS. The relationship between hearing impairment and cognitive function: A meta-analysis in adults. Clin Otolaryngol. 2015 Dec 16.

Shield B. Evaluation of the social and economic costs of hearing impairment. A report for Hear-it. 2006

Shiroiwa, T., Sung, Y.-K., Fukuda, T., Lang, H.-C., Bae, S.-C. and Tsutani, K. (2010), International survey on willingness-to-pay (WTP) for one additional QALY gained: what is the threshold of cost effectiveness?. Health Econ., 19: 422–437.

Sirven N, Bourgueil Y. La prévention de la perte d'autonomie : la fragilité en questions, apports, limites, perspectives. Rapport de l'IRDES n°563. 2016, janvier.

Sitbon A, Guignard R, Chan Chee C, du Roscoät E. Pensées suicidaires, tentatives de suicide et violences subies chez les populations sourdes et malentendantes en France. Résultats du Baromètre santé Sourds et malentendants, 2011-2012. Bull Epidémiol Hebd. 2015;(42-43):789-95.

UFC-Que choisir. Audioprothèses. Un marché verrouillé au détriment des malentendants. 2015, Septembre.

Viljanen A, Kaprio J, Pyykkö I, Sorri M, Pajala S, et al. Hearing as a predictor of falls and postural balance in older female twins. J Gerontol A Biol Sci Med Sci. 2009 Feb;64(2):312-7.