Hearing Loss and Hearing Gained: The Prevalence of Hearing Loss and Efficacy of Hearing Aid Donation in the Philippines

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Abstract

The limited data available on the prevalence of hearing loss in low and middle income countries indicate that it is highly prevalent and associated with a high burden of disease, such as delayed speech and language development, social isolation, and decreased educational and vocational attainment. This, coupled with a high rate of economic hardship and lack of public health services, suggest that there is a vast unmet need for hearing healthcare services. Philanthropic hearing aid donation programs attempt to bridge this gap, however, no research on the effectiveness of philanthropic hearing aid donation programs exists in the literature. This is partly because few locally translated and normed hearing aid outcome measures exist in many of these countries.

In a series of four papers focussed on the Philippines, this thesis investigates; the prevalence of hearing loss in adults and children, the effectiveness of a hearing aid donation program, and the psychometric properties of two translated outcome measures - the hearing handicap inventory short-form for adults and the elderly (HHIA-S and HHIE-S), and the international outcomes inventory for hearing aids (IOI-HA). Results show a high prevalence of hearing loss, compared with high income countries, and regional neighbours. In mild-severely impaired adults, the HHIA-S and HHIE-S showed psychometric properties similar to previous reports; but were insensitive to profound loss. The IOI-HA also showed psychometric properties in line with previous reports, however there was a lack of correlation to objective measures of hearing aid fitting. Additionally, the majority of donated hearing aids were broken or significantly under-fit six months after fitting. These findings highlight the high burden of disease of hearing loss in the Philippines, limitations of hearing aid donation programs, and limitations of outcome measures when applied in such populations.

Statement

I state that this work has been submitted exclusively to Macqaurie University (Sydney, Australia) for the consideration of a PhD degree.

The empirical content of this thesis is based on data collected at, and in conjunction with, the Centre for Audiological Science, University of Santo Tomas (Manila, Philippines).

Ethics committee approval was obtained for all relevant parts of this thesis (Macqaurie University Human Research Ethics Committee, ethics references: 5201100475 & 5201200581. University of Santo Tomas Faculty of Medicine and Surgery).

I certify that this thesis is my own work, except where joint work is expressly noted, and has not been submitted for a higher degree to any other university or institution. This thesis does not contain any unattributed material previously published or written by any other person. My supervisors; Catherine McMahon and De Wet Swanepoel have assisted with review of the manuscripts, and framing of the results and conclusions. Paper co-authors and anonymous reviewers (from journals to which the work was submitted) have contributed to the manuscripts. All co-authors have given permission for the manuscripts to be used in the thesis. Data collection was conducted by both staff at the Centre for Audiological Science, University of Santo Tomas (Manila, Philippines), in conjunction with Macquarie University Master of Clinical Audiology students under my supervision for all studies.

Chapter 2: I was the involved in the planning stages of this study and carried out all statistical analysis independently. I was the principal author of the study. The study was reviewed and edited by the co-authors.

Chapter 3: I was the involved in the planning stages of this study and carried out all statistical analysis independently. The first author was the principal author. I reviewed and heavily edited the study.

Chapter 4: I was the involved in the planning stages of this study and carried out all statistical analysis independently. I was the principal author of the study. The study was reviewed and edited by the co-authors.

Chapter 5: I was the involved in the planning stages of this study and carried out all statistical analysis independently. I was the principal author of the study. The study was reviewed and edited by the co-authors.

John Newall

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List of Abbreviations

4FA: Four frequency average

BTE: Behind the ear

FOG: Full on gain

Freq: Frequency

GDP: Gross Domestic Product

GNI: Gross National Income

HA: Hearing aid

HHI: Hearing Handicap Inventory

HHIE-S: Hearing Handicap Inventory for the Elderly (screening version)

HHIA-S: Hearing Handicap Inventory for Adults (screening version)

HRQoL: Health Related Quality of Life

HTL: Hearing Threshold Level

Hz: Hertz

ICF: International Classification of Functioning

IOI-HA: International Outcome Inventory for Hearing Aids

kHz: Kilohertz

LMIC: Low and Middle Income Countries

N: Number

NALSSPL: National Acoustic Laboratories Saturation Sound Pressure Level

$OSPL_{90}$: Output sound pressure level for a 90dBSPL input

PTA: Pure Tone Audiometry

%: Percent

REIG: Real ear insertion gain

REM: Real ear measurement

SD: Standard deviation

SEAR: South-East Asia Region

SES: Socioeconomic status

THD: Total harmonic distortion

UNHS: Universal Neonatal Hearing Screening

UST: University of Santo Tomas

VIF: Variance inflation factor

WHO: World Health Organization

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Chapter 1 - Introduction

1.1 Theoretical Framework

Hearing health and the availability and quality of habilitation and rehabilitation for those suffering hearing related disability varies dramatically across the globe, with economically disadvantaged regions suffering disproportionately (Duthey, 2013). The "WHO global disability action plan 2014-2021" outlines three objectives in its bid to reduce the impact of disability:

(1) to remove the barriers and thus improve access to healthcare,

(2) to improve habilitative and rehabilitative services, and

(3) to improve and encourage research on and into disability (World Health Organization, 2014).

The studies in this thesis provide evidence to support the three objectives outlined above. All four studies were conducted in the context of the Philippines, a lower middle income country with limited hearing healthcare services accessible to the general public. The Philippines was selected as the focus for this thesis due to the lack of existing literature on hearing loss and its rehabilitation in the country and in the region. The studies in this thesis add to the limited existing body of literature on hearing and ear disease and its rehabilitation in the Philippines. Further, several of the studies describe the translation and the psychometric properties of measures which can be utilised in future research to measure outcomes in this setting (Figure 1.1).

There are many ways in which access to hearing health care can be improved; the studies in this thesis indirectly address a few such avenues for improving access to hearing healthcare. Establishing a population's health care needs allows appropriate targeting of healthcare services, and is a key factor in improving access (Oliver & Mossialos, 2004). For accurate targeting of hearing healthcare services, the nature and prevalence of hearing loss and ear disease in the population must be known. The coverage and effectiveness of existing services must also be understood. This thesis presents studies investigating the prevalence and demographics of hearing loss, and the efficacy of an existing audiological rehabilitation program; both of which may assist in the goal of improved targeting hearing health care. The availability of prevalence and burden of disease data should also assist those advocating for greater funding for hearing health initiatives (World Health Organization, 2009). Furthermore public awareness may be raised by the publication and dissemination of such data, and this in turn may feed into advocacy efforts (Figure 1.1).

A broad evaluation of all Filipino hearing rehabilitation services is beyond the scope of this thesis. Instead, an example of one category of services; those delivered charitably, is evaluated in an effort to improve rehabilitation for the population of hearing impaired Filipino's with very low socioeconomic status (SES). As no published data exists on the topic, it is hard to estimate the exact proportions of rehabilitation services delivered philanthropically and privately (government funded rehabilitation services do not exist in the Philippines at the present time). The hearing aid outcome measures developed as part of the thesis may be useful, not only in future research, but also for clinicians, allowing them to ensure the effectiveness of the services they deliver.

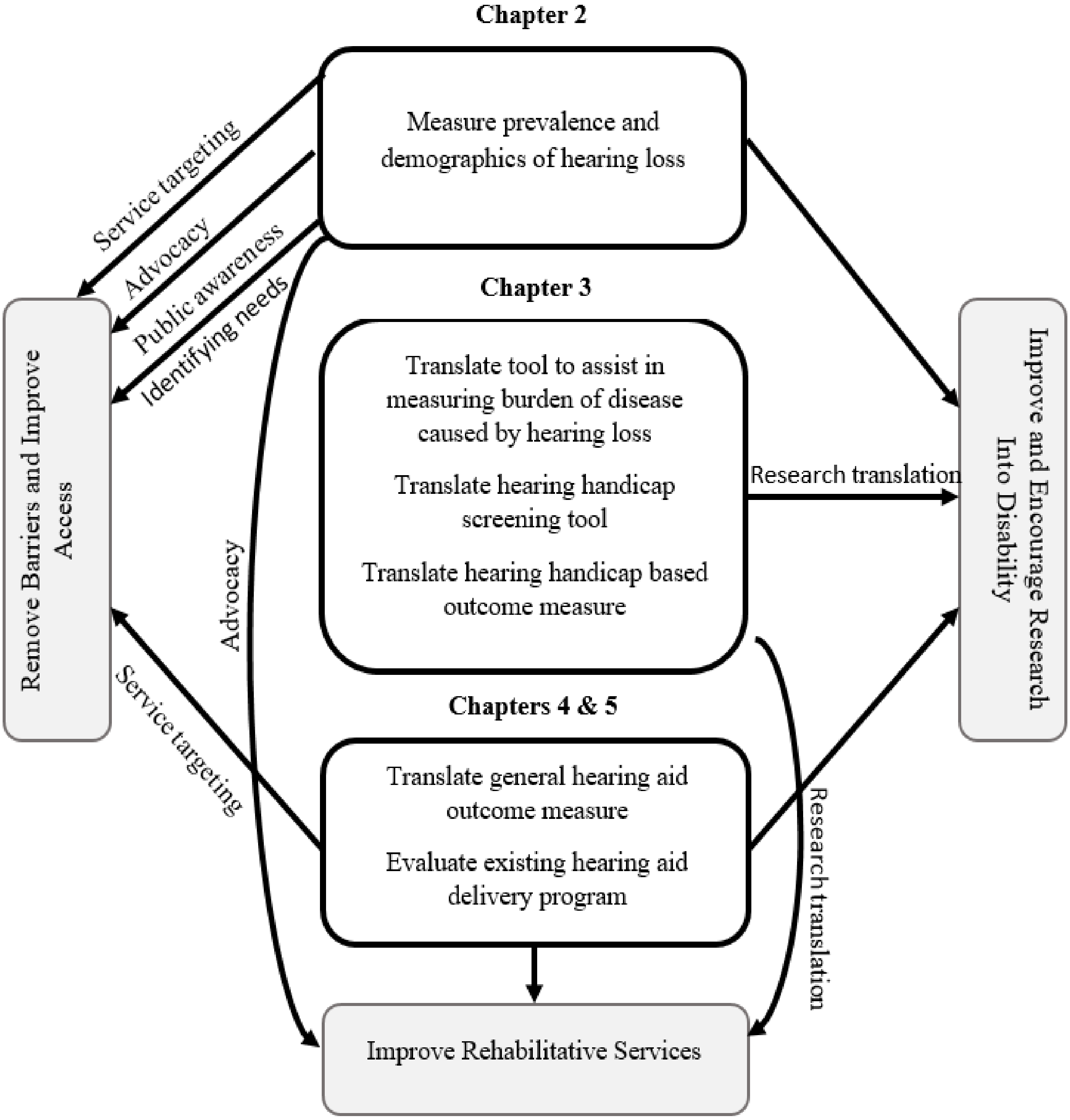

Figure 1.1 Components of thesis and their relationship to the WHO global disability action plan 2014-2021 objectives (World Health Organization, 2014).

1.2 Assessing the burden of disease

1.2.1 Global burden of disease caused by hearing loss

Recent estimates suggest that approximately 360 million individuals worldwide, or over 5% of the global population, suffer from disabling hearing loss (World Health Organization, 2013b), typically classified by average hearing thresholds (between 0.5, 1, 2, and 4 kHz) ≥41dBHL in adults, and ≥31 dBHL in children (World Health Organization, 2015). Hearing loss of this degree can result in significant communication difficulties, reduced social interaction, and social engagement. Negative impacts can be seen in terms of poorer educational and vocational status (Hogan, O'Loughlin, Davis, & Kendig, 2009), increased cognitive dysfunction (Uhlmann, Larson, Rees, Koepsell, & Duckert, 1989), poorer socio-emotional development/functioning (Hogan, Phillips, Brumby, Williams, & Mercer-Grant, 2015; Meadow, Greenberg, Erting, & Carmichael, 1981) and reduced quality of life (QoL)(Dalton et al., 2003). Hearing loss is the 5th leading cause of years lived with disability (YLD) (Vos et al., 2015).

The global burden of ear disease has been less well characterised in the literature, however recent data published by the Global Burden of Disease Study 2013 Collaborators (Vos et al., 2015) suggests that, looking at just one component of ear disease; acute otitis media, the global incidence is extremely high (4.48%) and contributes to the YLD attributed to hearing loss. Ear disease such as otitis media, tympanic membrane perforation, tinnitus, wax occlusion, and others can have an impact both in terms of the resultant hearing loss, but also because of a range of other morbidities and, in some cases, mortality that can result, particularly if the conditions are not treated or managed appropriately (Jamison et al., 2006). As a result, only a portion of the burden of disease associated with ear disease is captured by studies looking at the impact of hearing loss with the remainder partly captured within other disease categories such as upper respiratory tract infections and meningitis (Vos et al., 2015).

It appears that the burden of disease in general, and for hearing loss and ear disease specifically, is not equally spread amongst and across populations, but that those in the least economically developed regions and/or in the most socially and economically deprived groups suffer a disproportionate burden of disease. Underscoring this point, the WHO estimate that approximately 80% of those with disabling hearing loss reside in low to middle income countries (LMIC)(World Health Organization, 2013b).

1.2.2 Socioeconomic status, national development, and health outcomes

Socioeconomic status is a description of an individual's social position, education and economic standing. Strong and consistent associations exist between disease and illnesses and measures of socioeconomic status (SES) within high income countries (Adler et al., 1994), and within low income countries (Martorell & Habicht, 1986). With some exceptions, those in lower SES groups suffer a greater proportion of the burden of disease, with a gradient in between the two extremes (Adler et al., 1994). A similar relationship between hearing loss and ear disease has also been reported in the literature, with studies showing greater prevalence of hearing loss and ear disease in those with lower SES (Cruickshanks et al., 1998; Paradise et al., 1997).

Health outcomes are strongly, although by no means solely, associated with economic development (Deaton, 2001). The World Bank classifies countries into low, lower middle, upper middle, and high income groups according to their gross national income (GNI) per capita. Countries falling into the low to middle group are often referred to as "developing", with those in the high income group referred to as "developed". Given the variations in income, and education across countries, we might also expect to see a gradient in the burden of disease across low, middle, and high income countries. Indeed there are stark differences in both general health (Wilkinson, 2002) and hearing loss and ear disease (World Health Organization, 2013a), between the most and least economically developed countries. However the gradient between the two extremes is not as clear as expected. It appears that once a certain threshold of economic development is reached, further economic development has negligible effects on health outcomes (Wilkinson, 2002). Wilkinson (2002) contends that, material wealth is important up to a point, but beyond that point a much more important determinant of the population health outcomes are the levels of economic and social inequality within that region. The WHO (World Health Organization, 2013a) have developed a simple mathematical model describing the relationship between GNI per capita and prevalence of hearing loss in adults and children. The model grossly reflects the pattern of results previously discussed, predicting only a slow growth in prevalence across much of the GNI per capita range, with an exponential increase at the lower end of the income scale. One limitation of the model is that it was based on estimates of hearing loss prevalence for regions only, and it is thus unclear how closely the prevalence of hearing loss in specific countries (in particular the Philippines in the context of this thesis) matches the regional estimates.

The finding that economic development is not necessarily the primary driver of improved health outcomes has coincided with a greater interest in the impact of social, working, and living circumstances on the health of populations. Termed the “social determinants of health” the literature suggests that factors such as; social position, stress, early life development, social exclusion, work conditions, employment, social supports, addiction, food/nutrition, and transport may, be the primary drivers of many health conditions (Wilkinson & Marmot, 2003).

It appears that other than genetic factors; both income, material resources, and a range of social factors are important in population health outcomes, including the prevalence of hearing loss and ear disease. As both income, equality, and social conditions vary across nations this serves to highlight the importance of obtaining region specific data on the prevalence and impact of health conditions such as hearing loss and ear disease.

1.2.3 Hearing loss and burden of disease in low and middle income countries

While the literature investigating the prevalence and characteristics of hearing loss in high income countries, and its relationship to various relevant demographic variables is comprehensive (Agrawal, Platz, & Niparko, 2008; Cruickshanks et al., 1998; Davis, 1989; Fortnum et al., 2001; Gopinath et al., 2009; Hong et al., 2015; Moscicki, Elkins, Baurn, & McNarnara, 1985; Paradise et al., 1997; Stevens et al., 2013; Uimonen, Huttunen, Jounio-Ervasti, & Sorri, 1999; Van Naarden, Decouflé, & Caldwell, 1999). However, the literature is significantly less extensive in the context of LMICs. Pascolini and Smith (2009) provide a good review of epidemiological studies of hearing loss across LMIC. There are a small number of large population based studies (Al Khabori & Khandekar, 2004; Bu et al., 2011; Little et al., 1993; Wang et al., 2010), with the rest smaller, or more targeted studies, covering a number of different regions (Béria et al., 2007; Mann, Sharma, Gupta, & Nagarkar, 1998; McPherson & Holborow, 1985; Mishra, Verma, Shukla, Mishra, & Dwivedi, 2011; Prasansuk, 2000; Saunders et al., 2007; Westerberg et al., 2005). Considering prevalence rates in the afore mentioned literature, a relatively wide range of values are reported both across and within regions (Pascolini & Smith, 2009), but with rates generally significantly higher than those reported in high income countries. However, due to a lack of high quality, population-based epidemiological studies, the prevalence and characteristics of hearing loss in specific LMICs is challenging to predict. The variability and paucity of data supports the need for region specific, population based prevalence investigations.

1.2.4 Regional hearing loss prevalence data is important

One of the many factors limiting the effectiveness of health systems in LMIC is a lack of data on the prevalence, burden of disease, and characteristics of specific diseases or disorders. Bobadilla, Cowley, Musgrove, and Saxenian (1994) suggest that, as no health system has unlimited resources, there should be a focus on achieving the most effective and efficient use of health resources. To achieve maximal efficiency two key points must be considered; the burden of disease for each particular health condition within the population of interest, and the costs and effectiveness of potential interventions for those conditions.

For a clear understanding of the burden of disease to be obtained, data on the prevalence of the condition must be collected within each region. The benefit of such data is twofold. First, it allows for more accurate prioritisation and efficient allocation of health resources. Second, it serves to highlight relevant health issues and their effects, bringing them to the attention of political leaders, health workers, and the public (De Savigny, 2008; Pang, 2007). The second element needed for an appreciation of the burden of a particular disease is an understanding of the extent of the impact on those suffering from the condition.

1.3 Measuring hearing handicap

1.3.1 Health related quality of life

Quality of life is a global measure of an individual's wellbeing. Health related quality of life (HRQoL) describes the impact of specific health conditions on an individual's daily life or wellbeing. This impact can be in terms of physical, mental, or social changes engendered by the health condition (Guyatt, Feeny, & Patrick, 1993). Hearing loss and ear disease are just two among many conditions which have the potential to significantly affect an individual's HRQoL (Dalton et al., 2003). A number of general HRQoL measures are available; most notable the Short Form (36) Health Survey (Ware Jr & Sherbourne, 1992) and the WHO-

Disability Assessment Schedule II (World Health Organization, 1999). Both measures have previously been used to measure the impact of hearing loss on QoL and, although useful, have shown variable sensitivity (Chia et al., 2007; Chisolm, Abrams, McArdle, Wilson, & Doyle, 2005; Crandell, 1998; Dalton et al., 2003).

1.3.2 Hearing handicap and it association with hearing loss

The term hearing handicap specifically refers to the effect that hearing loss has on an individual's everyday function (Ventry & Weinstein, 1982). A range of measurements have been developed to investigate hearing handicap; the Social Hearing Handicap Index (Ewertsen & Birk-Nielsen, 1973), Glasgow Hearing Aid Benefit Profile (Gatehouse, 1999), the Hearing Handicap Inventory (HHI), for the elderly (Newman, Weinstein, Jacobson, & Hug, 1990), and adults (Newman, Weinstein, Jacobson, & Hug, 1991), amongst others. The benefit of such disease specific questionnaires is that they are more sensitive to the effects of hearing loss than more general QoL measures, allowing researchers and clinicians to investigate smaller impacts and changes in handicap following intervention.

Historically, hearing professionals have tended to judge the extent of an individual's hearing loss primarily through measures of hearing threshold. Conversely, for some time clinicians and researchers have noticed discrepancies between measures of an individual's hearing threshold and the self-reported effects on their daily life and well-being (Ewertsen & Birk-Nielsen, 1973). Indeed, when formally assessed, the association between hearing thresholds and hearing handicap is present, but only modest in strength (Lichtenstein, Bess, & Logan, 1988; Ventry & Weinstein, 1982). In part, the lack of a strong association may reflect the insensitivity of threshold measurements to deficits in temporal resolution, frequency selectivity, and a range of other physiological and psychoacoustical factors which also often accompany hearing loss, but that may vary between individuals with similar hearing thresholds (Moore, 1995). However, even accounting for these factors it appears that other, more contextual factors may be involved in mediating the impact of hearing loss on the individual (Ventry & Weinstein, 1982).

1.3.3 Towards a person-centred model of disease impact

The international classification of functioning (ICF) conceptualises the impact of a particular disease or condition in terms of the level of activity limitation and participation restriction suffered by the individual as a result of the disease related body and structure deficits. The ICF model also highlights the impact of context, with both environmental and personal factors potentially mitigating or extenuating the impact of a disease (World Health Organization, 2001). The model has previously been adapted and applied to understanding the effects of hearing loss in older adults (Danermark et al., 2010; Granberg, Swanepoel, Englund, Möller, & Danermark, 2014; Hickson & Scarinci, 2007), and assists in explaining the failure of hearing thresholds to capture the handicap associated with a hearing impairment. Further, it emphasises the need to carefully control for demographic variables when measuring the effect of disease. Factors such as age, gender, and socioeconomic status (SES), amongst others, can potentially mediate activity limitations and participation restrictions suffered by those with hearing loss (Hickson & Scarinci, 2007).

1.3.4 Hearing handicap as a screening tool

Measures of hearing handicap provide a clearer understanding of the burden of disease caused by hearing loss and ear disease, and thus may serve to stimulate public and governmental interest in hearing loss and ear disease, in turn serving an important public health function. Such measures may also serve several other functions; firstly as a means of identifying those in the population in need of rehabilitation, and secondly as a means of measuring the outcomes of hearing rehabilitation programs (to be discussed in the subsequent section). Traditionally screening for hearing loss in a population has relied upon conventional audiometry. The conduct of large scale screening programs for hearing loss using conventional screening audiometry requires specialised equipment, trained staff, and is administratively difficult due to the need for the patient to be physically present for assessment (McPherson & Olusanya, 2008). A self-report measure of hearing handicap provides an alternative to functional measures as a means of identifying hearing loss in a population (Gates, Murphy, Rees, & Fraher, 2003). If the goal is to identify individuals with hearing loss then, although the correlation between hearing handicap and hearing thresholds is modest rather than strong, it is still potentially a useful screening tool given that it does not require specialised equipment, trained staff, and can be provided to target populations remotely. From a philosophical standpoint, hearing health care professionals may be more interested in detecting the activity limitation and participation restriction associated with hearing loss than the measured level of hearing loss. Given that hearing loss is one of many proximal causes of such handicap, a screening measure targeted at identifying hearing handicap directly, rather than hearing loss per-se, might be preferred as a screening tool in some instances (Gopinath et al., 2012).

1.3.5 Hearing handicap as an outcome measure

As well as its potential as a measure of the impact of hearing loss, some have suggested that changes in hearing handicap can be used to assess the outcomes of a particular intervention (Newman & Weinstein, 1988). The relative worth of such a measure compared to other outcome measures (such as use, performance or satisfaction measures) is that it is theoretically closer to an indication of change in the individual's quality of life. From a public health perspective; increased rating of sound quality, high usage, and high rated satisfaction mean very little unless they actually translate into reduced disability.

A variety of studies utilising hearing handicap as an outcome measure have shown the benefits of hearing aids (Newman & Weinstein, 1988), cochlear implants (Noble, Tyler, Dunn, & Bhullar, 2009), and auditory training (Kricos, Holmes, & Doyle, 1992). The majority of these studies have been limited to investigating the success of hearing health interventions in high income countries.

1.4 Rehabilitation of hearing loss in low and middle income countries

1.4.1 Health interventions in LMIC

According to Bobadilla et al. (1994), the key to effective public health decision making is accurate determination of the prevalence and burden of disease in a particular region, and subsequently the identification of cost-effective interventions. In general, primary prevention type interventions tend to be maximally cost-effective and should be given priority in health budgets (World Health Organization, 2014). In terms of hearing loss and ear disease such primary prevention strategies might include; noise induced hearing loss prevention programs, and vaccination programs to reduce hearing related sequelae of infectious disease. However, secondary and tertiary intervention cannot be ignored; particularly in cases, such as hearing loss, where a sizable proportion of the disease burden is caused by factors not amenable to primary prevention strategies (presbyacusis, and congenital genetic hearing loss for example).

Given that hearing rehabilitation is a necessity, consideration must be given to the examination of the effectiveness of such programs in LMIC. Even in cases where the efficacy of an intervention has been shown in a high income context, care must be taken with directly extrapolating this data to a low and middle income context. Even more care must be taken when there are subtle differences in the delivery method, or devices and technologies used.

Similarly cost effectiveness cannot be directly inferred from studies in high income countries and should be examined independently (Baltussen & Smith, 2009). These considerations are of great importance when considering the limited funding available for health care programs in LMIC.

1.4.2 Health spending, human resources & existing health care services

A recent comparative analysis of health expenditure across countries suggest that, in general low and lower-middle income countries spend a lower percentage of gross domestic product (GDP) on health care, with the population also having greater out-of-pocket expense (proportional to GDP)(Kea, Saksenaa, & Holly, 2011). The WHO (2004, 2013a) reports a significant shortage of hearing health care services across LMIC, which is not surprising given the lack of funding for health care in general. A multi-country survey conducted by the WHO (2013a) suggested that fewer than half of the low and lower-middle income countries surveyed had a plan, program, or policy for ear care, or hearing loss prevention.

The delivery of both diagnostic and rehabilitation services for hearing loss and ear disease rely upon trained hearing health professionals. The WHO (2013a) report a severe lack of human resources in developing countries in terms of Ear Nose and Throat specialists, Audiologists, Teachers of the Deaf, and other ear health care workers. Along with the personnel shortages, a lack of training facilities to educate such professionals and a lack of primary ear care and diagnostic services for LMIC populations exist. Specifically considering the South-East Asia Region (SEAR), the WHO (2009) describes a significant shortage of primary and secondary level ear care and diagnostic services in the region, with a wide variation in the extent of the services provided across the regions surveyed. It is likely that this pattern of poor service provision is mirrored across the developing world.

Linked to the lack of diagnostic and primary ear care services are a lack of adequate rehabilitation services in LMIC. The WHO (2004) reports an unmet need for hearing rehabilitation across the globe; with production of hearing aids at only 10% of global need. Estimates suggest that only 25% of all hearing aids produced are supplied to those in LMIC. Given that the majority of those with disabling hearing loss reside in these countries this suggests a vast unmet need in these populations (World Health Organization, 2004).

1.4.3 Other barriers to access of hearing health care in LMIC

A variety of factors influence the availability of, and public access to hearing health care in LMIC. First and foremost, as discussed, a lack of diagnostic and rehabilitation service providers will clearly limit access. Wang and Luo (2005) identify a variety of other factors which may also hamper access to existing health care services; these factors can broadly be delineated into spatial (i.e. physical/temporal distance between health care users and providers) and non-spatial (eg. socio-economic and socio-cultural barriers to access) factors. A number of articles report hearing health care access being limited by spatial factors, in both the context of LMIC, and remote populations within high income countries (Sooful, Van Dijk, & Avenant, 2009; Swanepoel, Clark, et al., 2010). Socio-economic barriers are hinted at by the WHO's (2009) report on the variation in the extent of publically funded hearing services available across the LMIC in the SEAR. Finances have also been more directly identified as a factor limiting both the access to, and maintenance of, hearing aids in both high and LMIC (Kochkin, 2007; Sooful et al., 2009; World Health Organization, 2004).

These factors may interact to reduce access to health care for the majority of the population in LMIC.

1.4.4 Public and private hearing health care programs in LMIC

Examples of effective, publically funded hearing health care programs exist across a range of LMIC. Some focus on primary prevention (Daniell et al., 2006), some on early detection (see Leigh, Newall, & Newall, 2010; McPherson & Olusanya, 2008 for review), and some on intervention (Liu et al., 2011; Pienaar, Stearn, & Swanepoel, 2010). There are also private, user-pays hearing health facilities available in many LMIC (Olusanya, 2004). A recent WHO (World Health Organization, 2013a) report suggests that there are both insufficient publically unded services available in most LMIC, and because of financial disadvantage, private services are often not easily accessible to large segments of the population.

1.4.5 Charitable hearing health care programs in LMIC

In the absence of publically funded services in LMIC, it is common for under-served segments of the population to overcome the financial barriers of access to hearing health care by utilising services provided by charitable organizations (Mendoza, 2009; Schieber & Maeda, 1999). Although the precise legal definition of a charity varies across countries, in general a charitable organization is a type of non-profit/not-for-profit organization which provides services which are for the public good/in the public interest, and does not operate to provide profit to its members (Australian Charities and Not-for-profits Commission, 2015).

Hearing rehabilitation programs in LMIC have tended to focus on either hearing aids, or the development of signing (manual communication) programs, with the high cost of cochlear implants generally limiting the utility of this type of intervention (Zeng et al., 2015).

A number of such charitable programs exist in a hearing rehabilitation context, some closely aligned and funded by particular hearing aid companies and some independently run (ABC Tissue Hearing Express, 2015; Hear the World Foundation, 2015; Starkey Hearing Foundation, 2015; World Wide Hearing, 2015). Many of these programs offer a variety of services, including; diagnostic, rehabilitative, and surgical interventions, as well as training and upskilling for local health care workers. Although minimal published literature is available, it appears that some of the charitable programs offer rehabilitation services with technology and service delivery models similar to those seen in high income countries. Other programs appear to have adjusted either the delivery methods, technology, or both to suite the local conditions. Examples of such adaptations might be in the use of solar powered hearing aids (Deaftronics, 2015), non-programmable hearing aids (ABC Tissue Hearing Express, 2015; Starkey Hearing Foundation, 2015), or group based hearing aid orientation, and non-standard fitting verification techniques (Starkey Hearing Foundation, 2015).

Many charitable programs make an attempt to work with local organizations, however the level of integration, local training, and capacity building varies significantly. One criticism of such programs is that they rely too heavily on services delivered by overseas clinicians, whom fly-in to deliver services but soon fly-out again, leaving the population with little in terms of on-going support (Clark, 2013). Indeed the amount of locally available support or follow up has been suggested to be a key component in the success of all fly-in fly-out delivered health care (Clark, 2013; Wakerman, Curry, & McEldowney, 2012; World Health Organization, 2004). Lack of local support can lead to difficulties in accurately identifying populations in need of assistance and upkeep of hearing devices, provision of instruction, and re-adjustment of aids (Brouillette, 2008). Further, they may discourage local governments from taking ownership of the health problem and may thus lead to over-reliance on foreign aid and reduce local social health care spending (Mendoza, 2009).

Regardless of philosophical objections, charitable health care is a part of the current health care landscape in LMIC. Hearing rehabilitation services delivered by such charitable programs often differ from standard clinical practice, yet to date little attention has been paid to the evaluation of the efficacy of such programs.

1.5 Measuring the efficacy and effectiveness of audiological rehabilitation programs

1.5.1 Indicators of program efficacy

A range of measures have been suggested to evaluate the efficacy of hearing rehabilitation interventions. Questionnaire based measures of user; satisfaction, device usage, benefit, and quality of life following intervention are common methods utilised in the literature to judge the efficacy of an intervention, as are performance measures of benefit such as aided and unaided speech tests (Dillon, 2012). Some questionnaires focus on a single indicator of outcome, whilst others attempt to cover a wide range of outcome indicators.

Although normally used as a verification technique, measures of gain made on the real ear can be compared to prescriptive targets to appraise the quality of the fitting protocol. As to what would constitute an adequate fit to target, the literature varies, but converges on a figure of approximately +/- 6 dB from target (Baumfield & Dillon, 2001; Dillon, 2012; Mueller, 2005). Similarly measures of full on gain (FOG), total harmonic distortion (THD), and output sound pressure level for a 90dB input (OSPL90) made on a coupler can be compared to standards and used to assess the functionality of the hearing aids fitted through a hearing rehabilitation program (World Health Organization, 2004).

Another measure which does not relate directly to efficacy but is often considered when evaluating charitable programs, or health interventions in general, is the number of individuals treated (Starkey Hearing Foundation, 2015). Considerations such as these, although insufficient on their own, are important because many efficacy studies are run with small numbers of participants and issues of scalability of the program may need to be considered if the intention is to generalise the treatment to larger populations.

1.5.2 Limitations of current outcome measurement tools

Current outcome measures have generally been developed, normed, and largely utilised in high income countries. Those in LMIC may not be able to easily access and utilise such measures due to the language used and a lack of local translations. Even if local translations are undertaken there is no guarantee that the validity of the measure is retained, its norms and psychometric properties may be altered in the new cultural context. To ensure the outcome measure remains valid in the new translation and context a cultural adaptation should take place, and the questionnaire should be re-analysed in the relevant context (Beaton, Bombardier, Guillemin, & Ferraz, 2000; Guillemin, Bombardier, & Beaton, 1993; Wild et al., 2005). Both a lack of locally translated outcome measures and a lack of locally appropriate normative and psychometric data exist on such measures in LMIC.

1.5.3 Existing literature on efficacy of rehabilitation programs in high and LMIC

The efficacy of hearing aids as an intervention for those with hearing loss has been shown across a wide range of outcome measures, and across a wide range of ages, in high income countries (Kochkin & Rogin, 2000; Mäki-Torkko et al., 2001; Mueller, 2005; Mulrow, Tuley, & Aguilar, 1992). A smaller number of studies have shown the efficacy of hearing aid fitting undertaken in LMIC (Liu et al., 2011; Olusanya, 2004; Pienaar et al., 2010; Wong, Hickson, & McPherson, 2004). These studies have evaluated hearing aids fitted by standard clinical practice, with individualised pre–fitting, fitting, and post fitting care. The studies have included both analogue and digital devices, and have generally, although not exclusively, utilised real ear measures to fit the aids to prescriptive targets.

To date the literature does not report on the efficacy of programs utilising group based pre-fitting, fitting, and post fitting care, or on the efficacy of fitting the most basic types of hearing aid technology without real ear measurement. Yet, such practices are seen in charitable hearing aid donation programs (ABC Tissue Hearing Express, 2015; Starkey Hearing Foundation, 2015). This thesis presents an evaluation of the efficacy of one such program operating in Manila, Philippines.

1.6 The Republic of the Philippines

1.6.1 General demographic information

The Republic of the Philippines, hereafter referred to as “the Philippines”, is variously described as part of the East Asia and Pacific region or South-east Asia region. The population as of 2010 census was approximately 92 million (Philippine Statistics Authority, 2015). Over 95% of the population have at least basic literacy, with a corresponding number enrolling elementary schooling. The World Bank (The World Bank, 2015) reports a current GNI per capita of $3270 USD (figures based on 2013 data), with approximately 25.8% of the population living below the poverty line. With a GINI index of 0.43, the Philippines has one of the greatest income disparities in South-East Asia (The World Bank, 2015). Average life span is 67.6 for men and 73.1 years of age for men and women respectively, with an infant mortality of 23 per 1000 live births, with figures improving steadily over time. These statistics place the Philippines very much in the lower middle income category (The World Bank, 2015).

1.6.2 Health and Health care in the Philippines

Poorer health is linked to poorer economic development, but also to economic disparity within populations (Wilkinson, 2002), both characteristics that can be applied to the Philippines. It should not be surprising then, that global indicators of health such as infant mortality rates and average lifespan indicate significant limitations to health care and health standards in the Philippines.

Health care in the Philippines is delivered via a decentralised system, variously by; private, public, and non-government organizations (Langran, 2011). The majority of health care delivered in the Philippines is funded privately with approximately a 70% private, 30% public split of funding (Obermann, Jowett, Alcantara, Banzon, & Bodart, 2006; The World Bank, 2015). The structure of health care delivery is complex with services being delivered; in parallel (the same services can be obtained both publically and privately), in a sectoral fashion (available only via one source), in a group based fashion (some groups receive publically funded services whilst some do not), and lastly via a co-payment fashion (part payment supplemented by out of pocket expense to the user).

Universal health care coverage does not exist at present and there are significant gaps in the health care system both in terms of the groups covered by social health care and the accessibility of services for those who are covered. Groups such as workers in the informal sector, and poorer or indigent individuals, are not well covered by social health insurance and have little money to access private services (Obermann et al., 2006). Even those who are covered by some form of social health insurance may have trouble accessing services because of high co-payments (Mendoza, 2009), a factor compounded by the lack of regulation and enforcement of medical fees (Obermann et al., 2006).

Some health services are rarely covered by the social health care system. These services can range from certain surgical interventions (those considered as cosmetic), to some allied health services, and assistive devices such as hearing aids and cochlear implants (Mendoza, 2009).

1.6.3 Hearing Loss and Hearing Services in the Philippines

There exists both a committee for, and national plan for, ear and hearing health care in the Philippines (Better Hearing Philippines, 2015; World Health Organization, 2013a) as well as a national ear institute (National Insitutes of Health, 2015). The presence of such multidisciplinary groups with a plan of action is encouraging; however progress in successful advocacy and implementation of regulations can be problematic. Universal neonatal screening (UNHS) in the Philippines is a prime example of the difficulties translating advocacy into action. For many years advocacy groups petitioned for the establishment of a universal neonatal screening program, this culminated in the successful passage of the Republic Act No. 9709 in August of 2009, an act establishing mandatory newborn hearing screening within hospitals in the Philippines (World Health Organization, 2010). Although little literature exists examining the outcomes of this legislation, it appears that implementation of the legislation, although progressing, is extremely slow (Laguyo, 2014).

When compared to global, and particularly LMIC numbers, the supply of ear nose and throat specialists and audiologists in the Philippines could be considers fair, rather than poor or good (World Health Organization, 2013a). Access to these health professionals may however be limited by both spatial and non-spatial (particularly financial) barriers for large segments of the population, limiting the impact that these health care providers have on the populations ear health (Mendoza, 2009).

Hearing aids and associated hearing rehabilitation services can be obtained only privately or through charitable means in the Philippines; no publically run or funded clinics are available to the general public. Although there is no existing published literature to assess the accessibility of hearing aids and the associated hearing rehabilitation services in the Philippines it is clear that there is a significant unmet need for hearing rehabilitation amongst the financially disadvantaged segments of the population. A portion of the indigent population thus has its needs met by a variety of local and international charitable organizations. The largest local source of charitable funds for hearing aids is the Philippine appears to be the Charity Sweepstakes Office (2015), although other locally led and run charitable programs exist (Better Hearing Philippines, 2015). Internationally, several large groups and a large number of smaller groups are actively involved in delivering hearing aid services in the Philippines (Hear the World Foundation, 2015; Starkey Hearing Foundation, 2015; World Wide Hearing, 2015).

Although at present, no peer-reviewed publications on the prevalence of hearing loss in the Philippines exist, a population based survey of hearing loss and ear disease is described on the Better Hearing Philippines website (Better Hearing Philippines, 2005). The survey comprised 5971 participants, and provides prevalence estimates of disabling hearing loss in the left and right ears of the sample (13.4%, and 13.5% in the right and left ear respectively), although it does not provide data on the prevalence of disabling hearing loss in the better ear, and is not broken down by age group, making comparison of the data to previously published results difficult. Wax occlusion was common (11.9% of examined ears), as was perforation and otorrhea (5% and 2% of examined ears respectively). The prevalence of ear disease appears high when compared to figures from both high and LMIC (Karlsmose, Lauritzen, Engberg, & Parving, 2001; Moscicki et al., 1985; World Health Organization, 2009).

1.7 Aims of Thesis

The main aim of this thesis was to provide a better understanding of hearing loss and its management in the Philippines, and by extension in the developing world more generally. The prevalence, demographics, and correlates of hearing loss in Philippines have not been well reported in the literature. Yet such investigations are a key requirement for; improving the awareness of hearing loss in the community, targeting future hearing health care interventions and hearing loss prevention programs, and provide an evidence base to those advocating for increased government regulation and spending on ear and hearing health (Bobadilla et al., 1994; De Savigny, 2008; Pang, 2007; World Health Organization, 2009). Due to the significant economic hardship suffered by relatively large segment of the population in the Philippines (The World Bank, 2015), and to a lack of publically funded management options for those with hearing loss, the delivery of hearing rehabilitation through philanthropic means is common (although no data exists to confirm how common). There is almost no literature documenting the delivery of philanthropic hearing rehabilitation services and the outcomes of those receiving such services. Without investigation of the conduct and outcomes of philanthropic hearing rehabilitation programs, recommendations about how best to improve service delivery cannot be made.

1.8 Thesis Organization

Chapter 2 presents a population based study of hearing loss and ear disease in the Philippines. The relationship between hearing loss, ear disease and a variety of demographic variables is explored. The prevalence and character of hearing loss and ear disease in the Philippines is compared and contrasted to studies from other developed and developing countries.

The aim of Chapter 3 was to investigate the psychometric properties of Filipino (Tagalog) translations of the screening versions of the HHI. Such tools are needed to allow local clinicians and researchers to; establish the burden of hearing loss, screen for hearing loss, and assess outcomes following rehabilitative interventions. The psychometric properties of the HHI are contrasted and compared to previous reports in the literature to determine the adequacy of the questionnaires for use with the Filipino population.

Chapter 4 details the self-reported outcomes of a group whom had been fitted with hearing aids 6 months prior through a large scale hearing aid donation program. The chapter concomitantly describes the translation and psychometric evaluation of a Filipino (Tagalog) translation of the IOI-HA questionnaire. The objectively measured outcomes of the group of hearing aid recipients described in Chapter 4 are detailed in Chapter 5. Measures include; distance to prescription target as measured on the real ear, and a variety of test box measures ($OSPL_{90}$, FOG, and THD). The objective measures of hearing aid function and outcome are then compared to the subjectively reported outcomes (IOI-HA) to ascertain the concordance of the measures.

Chapter 6 presents a summary of the main findings of the thesis, a final conclusion, and indications for future research.

Chapter - 2 Hearing Loss in the Philippines

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Abbreviations: Four Frequency Average (4FA), Frequency (Freq.), Gross national income (GNI), Hearing Threshold Level (HTL), Hertz (Hz), Low or Middle Income Countries (LMIC), Pure-tone audiometry (PTA), Socioeconomic status (SES), South-East Asia Region (SEAR), University of Santo Tomas (UST), World Health Organization (WHO).

2.1 Abstract

Objective: To provide the first published national evaluation of the hearing loss prevalence in the Filipino population.

Design: A cross-sectional national survey was undertaken with survey regions selected utilising a three-stage stratified cluster design.

Study Sample: Participants included 2275 adults and children aged between 4 and 93 years of age.

Results: Prevalence of moderate or worse hearing loss was 7.4% in children <18 years, 14.4% in adults between 18-65 years, and 47.4% in adults >65 years. Factors associated with greater risk of moderate hearing loss in the better ear were: increasing age, higher income, and presence of a middle ear condition. Gender and rurality showed no statistically significant relationship to moderate or worse hearing loss in the better ear. Wax occlusion and outer and middle ear disease were very prevalent, with rates of 12.2% and 14.2% respectively.

Conclusions: Prevalence of hearing loss in the Philippines appears comparatively high across the age range when compared to rates reported in high income countries, with greater proportions of more significant loss. Hearing loss, particularly more significant losses, are a significant contributor to the national burden of disease in the Philippines.

2.2 Introduction

Hearing loss can cause significant difficulties with communication and social relationships, which can result in reduced health-related quality of life (Dalton et al., 2003), poorer education and vocational status (Hogan et al., 2009), increased cognition dysfunction (Uhlmann et al., 1989), and poorer socio-emotional development/functioning (Hogan et al., 2015; Meadow et al., 1981). Hearing loss is a significant contributor to the global burden of disease for both adults and children (Smith, 2008). The World Health Organization (WHO) estimates that there are 360 million people worldwide with a moderate or greater hearing loss, approximately 80% of whom reside in low or middle income countries (LMIC) (World Health Organization, 2013b). Hearing loss in LMIC has a high prevalence and a significant proportion of this burden is either preventable or treatable. Yet, when compared to other health conditions, little attention is paid to hearing loss prevention and remediation programs in these regions (Mencher, 2000; World Health Organization, 2004).

A number of large, high quality, epidemiological studies have investigated the prevalence of hearing loss in high income countries (Cruickshanks et al., 1998; Davis, 1989; Gopinath et al., 2009). While studies also exist for LMIC, their number and quality vary across regions (see Stevens (2013) for a review). Fewer, large, high quality, published studies exist reporting the prevalence of hearing loss across Asia (see Pascolini and Smith (2009) for a review). Two peer-reviewed studies exist in the local region surrounding the Philippines; one from a high income country, Korea (Hong et al., 2015), and one from a LMIC, Thailand (Prasansuk, 2000). Hong et al.'s (2015) study of hearing loss in Korea appears to show data comparable to high income countries in other regions. Prasansuk's (2000) study in Thailand, however, suggested a relatively high prevalence of hearing loss, with the estimated rates approximately three times those reported in high income countries (Davis, 1989). The WHO provide estimates of the prevalence of disabling hearing loss (average hearing thresholds ≥ 41dBHL) across Asia based upon both published studies and unpublished survey results. They report a prevalence of almost 9% for adults (≥15 years of age) and 2% for children (<15 years of age) for the Asia pacific region (of which they consider the Philippines a part)(World Health Organization, 2012b). Without epidemiological data on the prevalence and characteristics of hearing loss, prevention and management initiatives are unlikely to take place, and any efforts which are made may be misaligned to population needs (Mencher, 2000).

The present study reports epidemiological data on hearing loss, including prevalence estimates from a cross-sectional survey, collected in the Philippines in 2011. The Philippines represents a region with slower economic growth, and slower change in income inequality than many of the countries in the surrounding region (Balisacan & Fuwa, 2004; Gerson, 1998). Given the relationship between the social conditions of a population and their health outcomes (Marmot, 2005) we would expect a greater prevalence of hearing loss in the Philippines than both high income countries, and possibly even many of its LMIC neighbours.

2.3 Methods

Recruitment

A national cross-sectional survey of hearing loss and ear disease was conducted in the Philippines in 2011, led by staff from the University of Santo Tomas Faculty of Medicine and Surgery. The regions surveyed were chosen based on a three-staged stratified cluster design. The first step involved stratification into one of three separate regions (Luzon, Visayas, and Mindanao). In the second step, for each region two provinces were randomly selected. In the third step, for each of those two provinces, up to ten municipalities (barangays) were randomly selected. Households/participants were recruited from the chosen barangays by a quasi-random walk method. Survey teams of 2-4 members, including a mixture of audiologists, student audiologists, and ENT surgeons, started out from a well-populated local landmark and then approached every third house as they walked. A coin toss was used to decide survey team direction at intersections. At each house surveyed all residents were invited to participate in the study, regardless of age. If households declined to participate the researchers continued to the next household in the method described above. In total, 747 households agreed to participate in the survey with the average total occupants for each household 5.9 persons, although often not all occupants were available or consented to participate in the survey. The total survey population included 2896 individuals.

Materials and Apparatus

Two questionnaires were administered as part of the study (see Appendix A). The first was a self-report measures which requested demographic information including; the number of household members, employment, income, sanitation, water supply and housing structure was administered. The second questionnaire was administered by the survey team and requested information relating to history of hearing loss or ear disease. Results of the subsequent ear examinations and assessment were also recorded on this form.

For otoscopy, a Heine Mini 3000 was utilised. Audiometric results were obtained with either the Interacoustics AS208 Portable Screening Audiometer or the Path Medical Solutions Sentiero under supra-aural headphones (TDH39 and Sennheiser HAD 280 respectively).

Procedure

Written consent (in some cases verbally translated into the appropriate regional dialect) was obtained from the person identified as the head of the household. The head of the household was then asked to complete a demographic questionnaire on behalf of their family/household and was interviewed by a member of the survey team to complete the second hearing loss and ear disease questionnaire. Otoscopy was undertaken by the audiologist, student audiologist or

ENT surgeon, and results recorded. Wax occlusion was considered to have occurred when over 80% of the canal was obstructed (as approximated via otoscopy). Pure tone or play audiometric assessment was conducted by an audiologist in a quiet area of the participants own residence. Participants were tested to threshold (0dBHL minimum, 100dBHL maximum) at; 1000, 2000, 4000 and finally 500 Hertz (Hz), air conduction only (bone conduction was not conducted due to concerns regarding the noise floor). Participants responded by raising their hand or by play response. Ambient noise levels were not obtained at the time of testing.

Data analysis

All data was entered into IBM© SPSS© Statistics Package version 21(IBM Corp, 2012) for data analysis. Hearing loss was reported as a four frequency average (4FA) of PTA at 500, 1000, 2000 and 4000Hz and is presented for the better ear, except in the case of unilateral hearing loss where worse ear thresholds are reported. Unilateral hearing loss was defined as, better ear 4FA PTA < 25dB, and worse ear 4FA ≥ 25dB. Hearing loss was categorised according to the WHO (2015) recommendations, with a 4FA PTA of; ≤25dBHL indicating no impairment, 26-40dBHL indicating a slight impairment, 41-60dBHL indicating a moderate impairment, 61-80dBHL indicating a severe impairment, and >80dBHL indicating a profound impairment. Table 2.1 reports the demographic data of the sample, indicating that the sample did not match the Filipino population well in terms of gender and rural/urban distribution. All data was weighted to correct for the sample/population gender disparity for all subsequent analysis, including prevalence estimates and regression. Weighting to correct the samples rural/urban incongruity was not undertaken due to the extent of the disparity and is considered as a limitation of the paper in the discussion section. Binary logistic regression was run with all appropriate predictor variables included, the models presented in the analysis are shown with only significant predictor variables included. For the purposes of regression analysis, “hearing loss” was defined as a moderate or worse hearing impairment in the better

Table 2.1. Selected Unweighted Demographic Characteristics of the Sample

Demographic Characteristic		Frequency	Percentage (%)
Gender	Male	865	38
	Female	1410	62
Age	<18 years	778	34.1
	18-65 years	1308	57.6
	>65 years	189	8.3
Rurality	Rural	1744	76.7
	Urban	531	23.3
Income (Pesos)	Lower (≤5,000)	1256	55.2
	Higher (>5000)	1019	44.7
Family history of hearing loss*	Positive	247	10.9
	Negative	2007	88.2

*Note 11 cases of missing data relating to family history of hearing loss.

ear. The reasons for the focus on moderate or worse hearing loss in the better ear are two-fold. Firstly, the negative impacts of these more disabling levels of hearing loss are more consistently and clearly shown in the literature (Arlinger, 2003). Secondly, any elevation of the noise floor caused by measuring hearing thresholds in the participant's place of residence would be less likely to impact on the prevalence estimates of moderate (or worse) hearing loss.

2.4 Results

The participants in the current study included 2,275 adults and children recruited as part of a national cross sectional survey of hearing impairment in the Philippines. This group constitutes a subset of the larger survey population (of 2896 individuals) including all those cognitively able enough to complete pure tone audiometry (PTA).The participants' demographic details are shown in Table 2.1.

Otoscopic assessment results are shown in Table 2.2. Wax occlusion was common in the population with a prevalence of 17.8%, with perforation and abnormal tympanic membrane (defined as dull, retracted or red/bulging) being the next most common ear conditions. Overall prevalence of outer or middle ear disease (excluding wax occlusion) was also 17.8%.

Prevalence of moderate or greater hearing loss in the better ear was 14.9% across the whole population, with a prevalence of: 7.6% in children under 18 years of age, 14.7% in adults between 18 to 65 years of age and 49 % in adults over 65 years of age (Table 2.3.). Figure 2.1. shows the percentage of participants in each hearing loss category for each age group (by decade) . Four frequency average hearing thresholds in the left and right ear were 28.2 and 28.6 dBHL respectively. As can be seen in Table 2.3., there is only a small difference

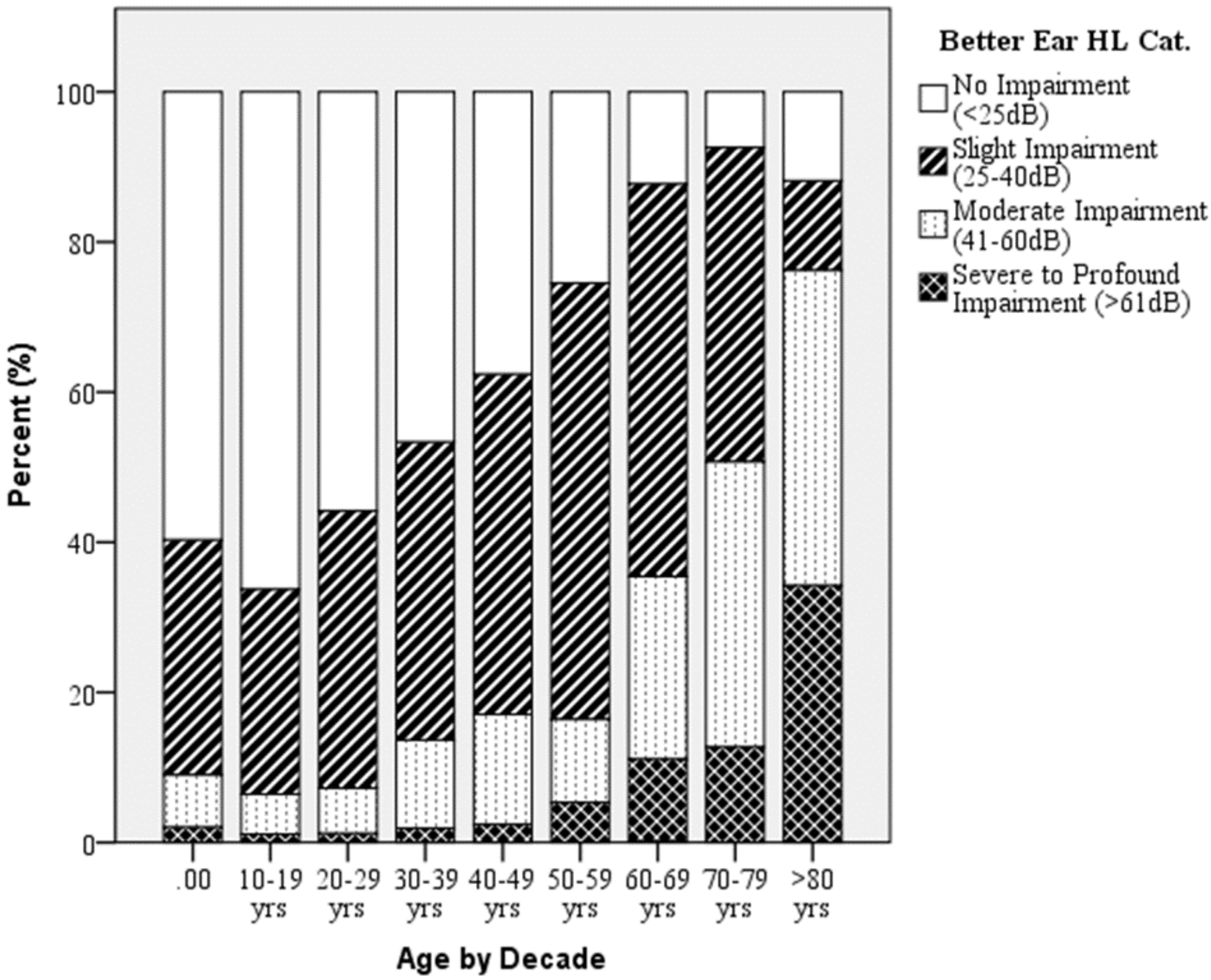

Figure 2.1. Better Ear Hearing Loss Category by Age Group (by decade)

between the prevalence of hearing loss in males and females; with females slightly more likely to have a slight impairment, and males marginally more likely to have a moderate loss or greater. Hearing loss category varied slightly with income level, with those in the lower income group tending have a lower proportion of mild hearing impairment, but a greater proportion of moderate or greater impairment than the higher income group (Table 2.3.). The prevalence of hearing loss across categories appeared similar in rural and urban populations (Table 2.3.). The prevalence of unilateral hearing loss across the whole sample was 19.6 %, with the majority having only a slight impairment in the worse ear (18.5%), and only a small proportion having a moderate (0.9%) or severe to profound unilateral impairment (0.2%).

Binary logistic backwards regression was used to assess the relationship between the presence of a moderate or worse hearing loss in the better ear and range of demographic predictor variables (independent variables). Note that due to a high degree of correlation between socio-economic status related variables, particularly income and housing related variables (water supply, sanitation, and structure), only two SES related variables (income and total number of house occupants) were used in the regression presented. When investigating income in the regression, due to the small numbers of respondents in the mid to higher level income groups, these groups were collapsed to form a higher income (≥ 5000 Peso) and a lower income group (<5000 Peso). After controlling for all other factors, only three variables; age, income, and outer or middle ear condition were found to be significant predictors of hearing loss, χ^2 (11) =246.254, p<0.000. A modest 18% (Nagelkerke's R^2) of the variance was explained by the model. Those with middle or outer ear conditions (with the exception of wax which was tested separately) were 2.36 times as likely to have a significant hearing loss as those without such conditions. Those with wax occlusion in the better ear were 1.58 times as likely to have significant hearing loss. Those in the higher income group were 1.44 times as likely to have a

Table 2.2. Weighted Frequency and Percentage of Ear Disease/Conditions in the Sample

Ear Condition		**Frequency (n)***	**Percentage of Ears (%)**
Ear Canal	Wax	405	17.8
	Otorrhea	79	3.4
	Infection	71	3.1
	Foreign body	9	<1
Tympanic Membrane	Perforation	142	6.2
	Abnormal	115	5.1

*n= number of ears

moderate or worse hearing loss than those in the lower income group. There was also a sharp rise in the odds of having a moderate or worse hearing loss as age increased (Table 2.4.).

2.5 Discussion

This is the first published study to investigate the prevalence of hearing loss and ear disease in a quasi-random sample of the Filipino population. The overall prevalence of moderate or worse hearing loss in the whole population was 14.9%, with a prevalence of 7.46% in children <18 years, 14.7% in adults 18-65 years, and 49% in adults >65 years. There was a significantly higher prevalence of hearing loss with ascending age group, indeed, for those above 50 years of age, the prevalence of moderate or worse hearing loss in the better ear approximate doubled with each subsequent decade (see Table 2.4.).

Over 17% of the ears in the present study were occluded with wax. Wax occlusion can cause discomfort, hearing loss and its sequelae (Guest, Greener, Robinson, & Smith, 2004). The WHO report data suggesting that between 2.9 and 15.9% of ears were wax occluded in various countries within the South-East Asia Region (SEAR), the current study prevalence rate falls just above the high end of this range (World Health Organization, 2009). Interestingly, Better Hearing Philippines (2005) presents a survey of hearing loss and ear disease in a population based study in the Philippines and reports a similarly high wax occlusion prevalence (11.9%) although not as high as in the present study. Middle ear disease was seen in 8.3% of the population, this figure is higher than the figures reported by the WHO (2009) in the rest of the SEAR; where 2 to 6% of ears were reported to suffer a middle ear condition. It is possible the figures in the current study are an underestimate of the true prevalence of middle ear disease in the Philippines, as undoubtedly some of those with outer

Table 2.3. Weighted Distribution of Hearing Loss Category by Demographic Variables

	Better Ear Four Frequency Average (0.5, 1, 2 and 4kHz) HTL							
Variable	No Impairment (HTL <25dB)		Slight Impairment (HTL = 25-40dB)		Moderate Impairment (HTL 41-60dB)		Severe to Profound Impairment (HTL >61dB)	
	n	%	n	%	n	%	n	%
Whole Sample	1063	46.7	872	38.3	260	11.4	81	3.5
Age (years)								
Children<18	523	62.9	245	29.5	50	6	13	1.6
Adults 18-65	521	41.5	549	43.7	146	11.6	39	3.1
Adults ≥ 65	19	10	78	41.1	64	33.7	29	15.3
Gender								
Male	548	48.2	410	36.1	135	11.9	43	3.8
Female	515	45.3	461	40.5	124	10.9	37	3.3
Income[a]								
Lower	586	47	492	39.4	134	10.7	36	2.9
Higher	477	46.4	379	36.9	126	12.3	45	4.4
Rurality								
Rural	821	47	669	38.3	194	11.1	63	3.6
Urban	242	45.7	203	38.4	66	12.5	18	3.4

[a] "Lower" <5000 Pesos, "Higher"≥5000 Pesos

ear conditions (such as infection, otorrhea, wax and foreign bodies) had middle ear conditions, but were undiagnosed due to difficulties visualising the tympanic membrane. The consideration of the inclusion of tympanometry in future surveys would help to elucidate the true prevalence of middle ear conditions.

There are a number of published hearing loss prevalence studies in the region surrounding the Philippines; of these, the data from the Thai population (Prasansuk, 2000) best approximates those of the current study. While this study does not include data with age gradations, data on the total prevalence of moderate, severe and profound hearing loss in the better ear show; 11.4% for moderate hearing loss and 2.2% for severe to profound loss. The current study reports very similar estimates, with prevalence's of 11.4% and 3.5% for moderate and severe to profound hearing loss respectively (see Table 2.3.). Comparative data from a Chinese population suggests a much lower prevalence with 4.1 and 1.9% with moderate and severe to profound hearing loss respectively (Wang et al., 2010). The prevalence of moderate or worse loss was also reported in a Korean population; with a weighted prevalence of 5.2% and 35.1% in those 19-64 years, and 65 years and older respectively (Hong et al., 2015). Comparative data from the current study suggests a higher prevalence; with 14.7% of 18-65 year olds and 49% of those older than 65 years with a moderate or worse hearing loss.

The WHO report on several unpublished surveys in the region surrounding the Philippines and suggest an overall population prevalence of moderate or worse hearing loss of between 4% to 16.2% (World Health Organization, 2009), the prevalence estimates from the current study fall within the high end of this range. Utilising a range of published data, and unpublished surveys Stevens et al. (2013) provide estimated prevalence data for disabling hearing loss across the entire SEAR region. The estimates are close to the current studies

Table 2.4. Odds Ratios of Moderate or Greater Hearing Loss by Demographic Characteristics

Factor		**Percentage of Sample (%)**	**OR (95% CI)**
ME in better ear	No	93.9	1 [reference]
	Yes	6.1	2.36 (1.53-3.65)***
Wax in better ear	No	87.5	1 [reference]
	Yes	12.5	1.53 (1.08-2.31)*
Income (Peso)	Lower <5,000	54.8	1 [reference]
	Higher ≥ 5,000	45.2	1.44 (1.12-1.85)**
Age (years)	< 10	19.2	1 [reference]
	10-19	19.7	0.8 (0.48-1.33)
	20-29	14	0.95 (0.55-1.66)
	30-39	13.8	1.79 (1.11-2.88)*
	40-49	10.8	2.32 (1.42-3.78)**
	50-59	10.1	2.31 (1.4-3.79)**
	60-69	6.8	6.42 (3.96-10.42)***
	69-70	4.4	12.99 (7.61-22.17)***
	≥80	1.2	32.01 (12.19-84.32)***

***Significant at p<0.001, **Significant at p<0.01, *Significant at p<0.05

prevalence rates for the 18-65 year old age group, but compared to the current study, overestimate the prevalence for older adults, and vastly underestimate the prevalence in children. Collectively; the data reviewed here serves to highlight significant regional variations in the prevalence of hearing loss in the areas surrounding the Philippines. As expected, clear differences exist when comparing the prevalence rates from the present study to those in the developed world, despite difficulties with comparison across hearing loss criteria and age categorisation. A representative study from the United States (Cruickshanks et al., 1998) is provided for comparison. This study report prevalence of hearing loss in the better ear (>25dBHL) of 60% for those over 60 years of age (Cruickshanks et al., 1998). In comparison, due primarily to extremely high rates of slight hearing impairment in the current study, prevalence rates of any level of hearing loss were substantially higher across all age groups (Table 2.3.). Sindhusake et al. (2001) and Davis (1989) also provide estimates of moderate or worse hearing loss in the better ear, with the former suggesting a prevalence rate of 15.6% in over 55 year olds (compared to 37.9% of adults >55 years of age in the current study), and the later a rate of 3.9% in over 17 year olds (compared to 18.9% of those >17 years old in the current study).

Although the previously discussed research focuses primarily on adult populations, there is a correspondingly large amount of data on paediatric populations as well. Studies of prevalence in older paediatric populations in high income countries vary but suggest rates that are approximately double that found in universal neonatal hearing screening. Uimonen, et al.(1999) found rates of just less than 2/1000 in 5-15 year olds, figures similar to those found in Van Naarden, Decoufle and Caldwell (1999) of 1.1/1000 for children 3-10 years of age,

Table 2.5. Prevalence and Proportion of Those Over 55 Years of Age by Hearing Loss Category

	Blue Mountains*		Philippines (current study)	
Hearing Loss Category	Prevalence (%)	Proportion of those with HL (%)	Prevalence (%)	Proportion of those with HL (%)
Mild	39.1	71.5	45.3	54.2
Moderate	13.4	24.5	26.4	31.7
Marked	2.2	4	11.7	14

* Adapted from Sindhusake et al. (2001). Validation of self-reported hearing loss. The Blue Mountains hearing study. International Journal of Epidemiology, 30(6), 1371-1378.

and in Fortnum et al. (2001) of up to 2/1000 for under 9 year olds. The rates in the current study are well over an order of magnitude higher (7.6/100 in children <18 years of age).

In order to facilitate comparison with data from a previous study of hearing loss prevalence in an older Australian population (Sindhusake et al., 2001), hearing threshold data for those 55 years or older was reclassified into mild (4FA= 26-40dBHL), moderate (4FA= 41-60dBHL), or marked (4FA>60dBHL). Of those with a hearing loss of any level, the proportion falling into each category was then calculated and is shown in Table 2.5. A greater proportion of moderate or worse hearing loss, and a lower proportion of mild hearing loss was seen in the current study than in the comparison population (Table 2.5.). This finding suggests that, not only is there a higher prevalence of hearing loss in the Filipino population, but that of those with a hearing loss, there is a greater share of the population with disabling levels of loss than in a high income comparison population. It should be noted that care should be taken interpreting the comparative data presented here as the specific age distributions of the samples was not matched. Wang et al. (2010) report data from a sample of the Chinese population and, although not discussed by the authors of that paper, their data appears to show a pattern similar to the data in the current study. Direct comparison is difficult because of different age gradations, but in those over 50 years of age, of those with hearing loss, approximately 62%, 26%, and 12% of losses were mild, moderate, and severe to profound respectively (see Table 2.5. for comparative figures)(Wang et al., 2010). It is unclear whether this pattern is characteristic of all, or at least many developing countries, as this appears to be the first time such a comparison has been made in the literature. It is probable that these differences are in part reflective of variations in the proportions of the various aetiologies underlying hearing loss in LMIC and high income countries.

The designation of countries as; high, low, or middle income is broad, which somewhat arbitrarily delineates a range of countries into three groups which more accurately fall along a spectrum of income and development. A more continuous measure of a countries development such as the Gross National Income (GNI) per capita can also be compared to prevalence of hearing loss. The WHO (2013a) has derived a model that predicts an exponential increase in the rates of hearing loss for the most economically challenged regions. Given the per capita GNI, the WHO model can then be used to predict a prevalence rate for child (<14 years) and older adult (> 65 years) hearing loss in a particular country or region. Using the World Bank GNI per capita estimate for the Philippines ($2210 USD) (The World Bank, 2013), the WHO model predicts a prevalence for childhood (< 14 years) disabling (moderate or worse) hearing loss of approximately 2%, whereas the prevalence rate in the present study is approximately 8.1%. It should be noted that, for children, the WHO model defines disabling childhood hearing loss as 4FA≥31dBHL, whereas the current study used a definition of 4FA≥41dBHL. This discrepancy means that the direct comparison of prevalence rates in the present study and the WHO model should be interpreted with caution. For the older adult population (> 65 years) the WHO model predicts a prevalence of approximately 44%, the current study found a prevalence rate of 49%. The current study therefore appears to validate the WHO model for older adults, but suggests that the model under-estimates the prevalence of hearing loss in paediatric populations at the lower end of the GNI per capita scale. Given that the WHO models were derived from regional averages it is perhaps not surprising that the model will not precisely predict specific country level prevalence rates, in this sense the data evaluations provided simply emphasise that significant variations in the relationship between hearing loss prevalence and GNI per capita can exist within regional groups.

The literature variously reports both a higher prevalence of hearing loss in those who live in rural areas (Mann et al., 1998; Minja & Machemba, 1996; Mishra et al., 2011), and a failure to find a relationship between rurality and hearing loss (Bastos, Mallya, Ingvarsson, Reimer, & Andréasson, 1995; Wang et al., 2010). The current study, in line with the latter studies, found no relationship between rurality and prevalence of hearing loss. The current study also failed to find a relationship between gender and hearing loss prevalence. A fairly robust relationship is commonly reported in the literature, with males showing a higher prevalence, although rates do vary regionally (for a review see Mathers, Smith, & Concha, 2000). The findings of the current study are hard to interpret, but may reflect some sampling bias. Males were more likely to be absent from home during the survey data collection and hence females were over-represented in the sample, weighting of the data was undertaken prior to analysis but may have failed to adequately account for the sampling bias.

Previous epidemiological studies have found associations between socioeconomic status (SES) and hearing loss, with lower SES linked to greater prevalence of hearing loss (Agrawal et al., 2008; Cruickshanks et al., 1998; Kubba, Macandie, Ritchie, & MacFarlane, 2004; Paradise et al., 1997). Unlike much of the previous literature the current study found a positive association between SES (income) and hearing loss, with those in the higher income group more likely to have a moderate or worse hearing loss in the better ear. This may, in-part, be due to that way which income was classified in the current study; with the lowest income group compared to those in all other higher income groups combined. Larger studies allowing non-clustered income groups or alternative measures of SES, and the inclusion of questions relating to noise exposure would elucidate the link between SES and hearing loss in the Filipino population more clearly.

Some limitations with the current study should be noted. The prevalence of slight hearing impairment was extremely high across the age range (see Figure 2.1.). Testing was conducted in the participants' home environment and, even though all care was taken to reduce intrusive noise during testing, the likelihood that noise contamination influenced hearing testing results in some cases was high. Due to the relatively small size of the current study it is unlikely that the sample is an accurate representation of the population of the Philippines, inferences about the population should therefore be made with this limitation in mind. Indeed, examination of the demographic characteristics of the sample reveals some clear disparities between the sample and the Philippine population as a whole (National Statistics Office, 2010, 2012). The rural/urban ratios were skewed, with the rural population being greatly over-represented in the current study, this is most likely due to chance, as the areas selected for survey by the study were randomly selected. The decision was made not to weight the sample data to correct for the rural sampling bias due to the extent of the disparity between the sample and population, this should be considered when interpreting the data and is a significant limitation of the study. As previously mentioned, females were very over-represented in the sample and although weighting of the data was undertaken to adjust for the sample bias this should still be considered when interpreting the result of the study. Although variations in the reporting of data by the National Statistics Office make direct comparisons difficult, the age gradations of participants in the current study approximately resembled those of the whole population, as does the monthly income.

2.6 Conclusion

The current study indicates that prevalence of moderate or worse hearing loss in the Filipino population is high across all age groups when compared to prevalence estimates reported in high income countries, and falls within the higher range of prevalence rates reported in LMIC.

Higher proportions of more significant hearing loss were also found when compared to reports from high income countries. The high burden of disease resulting from hearing loss pose a challenge to those involved in allocating health resources in regions, such as the Philippines, where resources are limited and other health priorities often take precedence. The high prevalence of preventable ear disease such as wax occlusion and outer and middle ear disease suggest that some simple hearing health care initiatives, such as giving basic ear care and hygiene training to local doctors/health care workers could have a significant impact, particularly in children and the elderly. There were a number of anomalous findings in this paper; the failure to find increased risk of hearing loss in males and those in rural areas, and the apparent increase in risk of hearing loss in those with higher SES. These variations are likely explained by a combination of; bias in participant recruitment, variations in the classification of demographic variables, and true underlying population differences. Future studies should aim to address these limitations and should consider obtaining data on workplace and recreational noise exposure.

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Declaration of Interest

The authors report no declarations of interest

Chapter 3 – Measuring hearing handicap, a profound conundrum. Discovering the limitations of a Tagalog translation of the Hearing Handicap Inventory for the Elderly and Adult Screening Questionnaire

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Abbreviations: 4FA: Four frequency average of the better ear, HRQoL: Health Related Quality of Life, HHI: Hearing Handicap Inventory, HHIE-S: Hearing Handicap Inventory for the Elderly (screening version), HHIA-S: Hearing Handicap Inventory for Adults (screening version), ICF: The International Classification of Functioning, Disability and Health, WHO: World Health Organization

3.1 Abstract

Objective: Measures of hearing handicap have typically been developed and assessed in high income countries. This study aims to evaluate the sensitivity of a Tagalog translation of the HHIE-S and HHIA-S questionnaires in a lower middle income context; the Philippines.

Design: Prospective study.

Study sample: 309 participants (18-86 years) were recruited from a population attending a hearing aid donation program in Manila, Philippines.

Results: The average hearing handicap inventory (HHI) total score was high (26.28) consistent with the high mean hearing threshold (85.7dBHL), however simple correlation and regression revealed no relationship between hearing threshold and HHI score. Subsequently mild to severe, and profound subgroups were delineated. A positive relationship between hearing threshold, and a negative relationship between SES and HHI score was seen in the mild to severe group but not in the profound group. MANOVA suggested different response patterns on the HHI for the two subgroups. Principal component analysis revealed two factors in the HHI that varied somewhat from the emotional and social subscales intended in the original questionnaire.

Conclusions: This study suggests that the HHIE-S and HHIA-S questionnaires are not sensitive to the handicap caused by profound hearing loss. The cause of this lack of sensitivity is not clear but may reflect a ceiling effect. Alternatively, self-rated hearing handicap may be reduced in those exposed to manual communication, or in those whom have a congenital hearing loss but whom have received minimal intervention.

3.2 Introduction

Over 360 million individuals worldwide have some form of hearing loss that affects daily living; defined as pure tone average hearing loss > 40dB in the better ear for adults. The prevalence of such disabling hearing loss in a particular population can be affected by factors such as; genetics, age, and socio-economic status (SES) (Kubba et al., 2004; Wiley, Cruickshanks, Nondahl, & Tweed, 2000). The prevalence of disabling hearing loss vary across regions and is greater in lower and middle income countries (LMIC) than in higher income countries, significantly reducing the quality of life and increasing the burden of disease in these populations (World Health Organization, 2012b).

Untreated hearing loss can cause activity limitations and participation restrictions which may lead to a range of social and emotional impacts such as; social isolation, reduced quality of family life, depression, and anxiety or, more globally, a reduced quality of life (Lotfi, Mehrkian, Moossavi, & Faghih-Zadeh, 2009; Monzani, Galeazzi, Genovese, Marrara, & Martini, 2008; Morgan, Hickson, & Worrall, 2002). Both generic and disease specific HRQoL measures exist, with both types showing significantly reduced HRQoL in those with hearing loss (Dalton et al., 2003; Gopinath et al., 2012). Hearing handicap describes the negative impact on HRQoL related specifically to hearing loss. The outcomes of hearing rehabilitation programs can be evaluated in terms of changes in hearing handicap following intervention, and indeed a range of hearing aid programs have been shown to produce significant improvement in hearing handicap (Chisolm et al., 2007). Lastly, such measures can and have been used to screen populations for hearing impairment, further discussion of the relationship between hearing loss and measures of hearing handicap is provided below. Whilst hearing handicap has been investigated quite extensively in the context of high income countries (Chia et al., 2007; Chisolm et al., 2007; Dalton et al., 2003; Gopinath et al., 2012) little attention has been paid to hearing handicap and its relationship to hearing loss in LMIC.

Associations between severity or level of hearing loss and hearing handicap have been reported; with more significant loss associated with greater activity limitation, participation restriction and greater hearing handicap (Dalton et al., 2003; Lichtenstein et al., 1988). Despite the clear association between degree of hearing loss and hearing handicap, previous research has described only a moderate correlation between the degree of hearing impairment and the impact of hearing loss, with correlations ranging between r= 0.29 to r=0.69 (Lichtenstein et al., 1988; Tomioka et al., 2013; Ventry & Weinstein, 1982). Hearing handicap may be influenced by environmental factors, personality factors, as well as cognitive resources which could mitigate some of the handicapping effects of a pure tone loss (Pichora-Fuller & Singh, 2006). Measures of hearing handicap have also been show to more strongly correlated with global measures of quality of life than audiometric thresholds (Gopinath et al., 2012). Given these findings, it appears that hearing handicap can be more accurately measured using a self-report rather than inferring it from audiometric results (Ventry & Weinstein, 1982).

Several self-report questionnaires designed to measure hearing handicap exist (Barrenas & Holgers, 2000; Ewertsen & Birk-Nielsen, 1973; Gatehouse, 1999), with some of the best used and validated being the short (10 question) and long (25 question) forms of the Hearing Handicap Inventory (HHI) (Ventry & Weinstein, 1982). Versions for the elderly (≥65 years) and for adults (<65 years) exist in the long and short format, differing only slightly in the wording of 3 and 2 questions respectively. All versions of the questionnaire attempt to quantify both the social and emotional impacts of hearing loss, and contain social and emotional subscales (Newman, Jacobson, Hug, Weinstein, & Malinoff, 1991; Newman et al., 1990; Ventry & Weinstein, 1983; Ventry & Weinstein, 1982; Weinstein, 1986). The screening questionnaire was shown to be comparable in internal reliability (α= 0.87) to the full form (α= 0.95), as measured with Cronbach's alpha (Ventry & Weinstein, 1983). In addition, high correlations were reported between the social and emotional subscales, and the overall score (r= 0.96 and 0.97 respectively), as well as between the social and emotional subscales (r=0.86) (Aiello, Lima, & Ferrari, 2011). All versions of the HHI questionnaire have been extensively, validated and reviewed and are considered to be robust and reliable measures in a number of English-speaking populations such as the United States (Gates et al., 2003; Newman et al., 1990; Ventry & Weinstein, 1983), Canada (Ciurlia-Guy, Cashman, & Lewsen, 1993), and Australia (Sindhusake et al., 2001). The Hearing Handicap Inventory for the Elderly (HHIE) specifically, has also been found to have a high convergent validity with other questionnaires measuring hearing handicap and quality of life (Chisolm et al., 2005).

Recently, both the shortened versions of the HHI have been translated into a number of other languages and have been used with speakers of Japanese (Tomioka et al., 2013), South Indian languages (Deepthi & Kasthuri, 2012), Finnish (Salonen, Johansson, Karjalainen, Vahlberg, & Isoaho, 2011), Italian (Monzani et al., 2007), Portuguese (Aiello et al., 2011), and Spanish (Lichtenstein & Hazuda, 1998). Research is needed to validate each non-English translation to investigate the cultural appropriateness of the questionnaire. Each study confirmed the robustness and reliability of the translated HHI in the context of the participants within the study. Values obtained for sensitivity, specificity, reliability and test-retest reproducibility were similar to those values obtained in the original English versions (Aiello et al., 2011; Deepthi & Kasthuri, 2012; Monzani et al., 2007; Salonen et al., 2011; Tomioka et al., 2013; Ventry & Weinstein, 1983).

Despite the extensive use and study of the HHI there have been no reports verifying that the questions underlying the two purported emotional and social subscales identify two distinct factors. There is also little published literature validating hearing handicap instruments, such as the HHI, in LMIC. The potential difference in the prevalence, degree and type of hearing loss and the stark socioeconomic, cultural and linguistic differences between developed and developing nations necessitate that screening questionnaires be verified independently for such populations.

The current study aims to evaluate hearing handicap in a Filipino population utilising a Tagalog translation of the screening version of the HHI. An investigation of the psychometric properties of the questionnaires, including factor analysis to evaluate the subscales was also conducted.

3.3 Methods and materials

Participants

The participants in the current study were drawn from a larger group of 1200 individuals presenting for a hearing aid donation program. Participants under the age of 18 were excluded from the study. A convenience sample of 610 individuals were approached to participate in the study. Of the 610 people approached, those with absent audiometric results or incomplete HHI questionnaires were excluded. Three hundred and nine participants (131 males and 178 females), age range 18-86 years (with a mean age of approximately 47 years) fulfilled the inclusion criteria.

The most common level of reported educational attainment among the sample was 'High school' (n=101, 34.35%). More than half of the participants who reported their income (n=134, 58.26%) were in the lowest income category, putting them below the poverty line. The demographic information of the population is summarised in Table 3.1.

This study was approved by the Faculty of Medicine and Surgery at the University of Santo Tomas and the Macquarie University Human Research Ethics Committee.

Assessment procedures

Participants were drawn from a population attending a hearing aid donation program in metropolitan Manila. Audiometric data was collected from participants that had been tested either on or prior to the day. All consenting participants were issued with either the hearing handicap inventory for the elderly screening version (HHIE-S), or the hearing handicap inventory for adults screening version (HHIA-S) at the registration desk prior to the fitting of a hearing aid. Participants 65 years of age or older completed the HHIE-S; those below 65 years completed the HHIA-S. Participants were asked to complete the questionnaires independently using pen and paper administration.

Questionnaire

A native Tagalog speaker translated the original English version of the HHIE-S and HHIA-S into Tagalog. This translation was subsequently reviewed by two independent native speakers of Tagalog. The final translation was negotiated and agreed upon by the reviewing translators prior to the distribution of the final paper version. The total score was calculated by adding the scores of the 10 individual questions, each of which were scaled; never=0, sometimes=2, always=4. Scores could thus potentially range from 0 (no handicap) to 40 (maximum handicap). The items 1, 2, 4, 7 and 9 were added to compute the emotional subscale score and the items 3, 5, 6, 8 and 10 were added to compute the perceived social effects subscale score, as per the original questionnaire's design (Ventry & Weinstein, 1983). Participants were asked to complete a self-report form about their monthly family income and educational attainment, as well the questions; "Do you feel that you need a hearing aid?", and "How confident are you in your ability to manage/use a hearing aid?".

Pure Tone Audiometry

Pure tone air conduction audiometry was carried out by audiologists and supervised audiology students, utilising calibrated audiometers with supra-aural headphones, in sound treated booths. The testing consisted of four frequency air conduction testing only and a four frequency average (4FA) hearing threshold (500 Hz-4 kHz) was derived for both ears. Hearing loss was classified utilising the World Health Organization (WHO) criteria (Mathers et al., 2000) as; *normal* (≤25dB), *mild* (26-40dB), *moderate* (41-60dB), *severe* (61-80dB), or *profound* (≥81dB) as determined by the 4FA of the better ear.

Statistical analysis

Data was analysed using *R v3.0.2,*(R Development Core Team, 2013); an open source statistical program for Windows, and IBM© SPSS© Statistics Package version 21 (IBM Corp, 2012). Due to the similarity of the two questionnaires the data for the HHIE-S and HHIA-S were pooled for analysis.

The internal consistency of the HHI was assessed with Cronbach's alpha coefficient. In order to establish how each item affected the reliability of the scale, Cronbach's alpha was also calculated when each item was removed from the scale. The criterion validity of HHIS score as a predictor of pure tone audiogram results from the better ear was measured with Pearson's correlation coefficient.

Principal component analysis with varimax rotation was used to extract factors from the 10 HHI items to determine the validity of the social and emotional subscales. The optimal

Table 3.1. Participant demographic and study characteristics.

	n	Mean	SD	Range
Age	309	46.95	19.69	18-86
4FA (better ear)	309	85.74	29.45	10-130
HHIE-S/HHIA-S SCORE	309	26.28	9.82	0-40
Normal (≤25 dBHL)	8	22.25	9.47	8-34
Mild (>25 dBHL)	12	18.33	10.51	4-38
Moderate (>40 dBHL)	42	24.48	11.29	2-40
Severe (>60 dBHL)	75	30.00	8.47	4-40
Profound (>80 dBHL)	172	25.84	9.44	0-40
Educational attainment	*Total responses*	**%**		
Others	24	7.77%		
Vocational	16	5.18%		
Elementary	57	18.45%		
High school	101	32.69%		
College	68	22.00%		
Postgraduate	28	9.61%		
Perception of hearing aid need				
No	6	1.94%		
Sometimes	10	3.24%		
Yes	286	92.56%		
Confidence in managing a hearing aid				
Not at all	12	3.88%		
Moderately confident	49	15.86%		
Very confident	232	75.08%		
Monthly Income				
less than P5,000.00	134	43.37%		
P5,001.00 - P10,000.00	51	16.50%		
P10,001.00 - P15,000.00	19	6.15%		
P15,001.00 - P20,000.00	16	5.18%		
P20,001.00 - P25,000.00	6	1.94%		
More than P25,000.00	4	1.29%		

number of factors was determined by Cattell's Scree test. Multi-linear regression analysis was performed to investigate the effects of personal and demographic variables on total HHI scores. For the purposes of regression analysis income group was coded as; low (comprising the lowest income group), or high (comprising all other income groups). Similarly education was dummy coded, with all those with secondary or lower educational attainment making up the "low" education group, and those who completed college or post-graduate degrees falling into the "high" education group. Multiple analysis of variance was used to determine if the mild to severe and profound subgroups differed in their pattern of responses across items on the HHI.

3.4 Results

Audiometric Results

The better ear, mean 4FA hearing threshold for the whole sample was 85.7dBHL, indicating a profound hearing loss (Mathers et al., 2000), and the most frequently occurring degree of hearing loss was also profound (n=172, 55.7%).

Questionnaire responses

The majority of participants (n= 232, 79.18%) reported that they felt 'very confident' with hearing aid management. Similarly, the majority (n=286, 94.70%) of participants reported that they felt that they 'needed' a hearing aid. Analysis of the distribution and correlation of individual questions on the HHI showed mean scores for each item ranged from 2.14 to 3.07 (SD: 1.33-1.69) with an overall mean of 26.28 (SD: 9.82).

Audiometric correlates

Correlations between the 4FA of the better ear and total HHI score were calculated using Pearson's correlation coefficient which yielded a score of r=0.02 (p=0.67). The lack of correlation between hearing threshold and HHI score, which has been a robust finding in previous studies (Salonen et al., 2011; Ventry & Weinstein, 1983; Wiley et al., 2000), and the high number of profoundly hearing impaired individuals, suggested the need to separate the population into two subgroups. One subgroup was made up of those with better ear hearing thresholds ≥ 81dBHL (average 4FA=107.6dBHL, n=172) (hereafter referred to as the profound hearing loss group), the second subgroup was made up of those with better ear hearing thresholds < 81dBHL (average 4FA=58.3dBHL, n=137) (hereafter referred to as the mild to severe hearing loss group). Much of the subsequent analysis was performed on each subgroup independently. Participants with a profound hearing loss showed a mean HHI score of 25.84 (SD: 9.44). For participants with a mild to severe hearing loss the mean score on the HHI was 26.83(SD: 10.29).

Pearson's correlation coefficient for the mild to severe subgroup (4FA <81dB) showed a significant correlation between 4FA and hearing handicap score r= 0.35 (p<0.0001) indicating increasing handicap with increasing hearing loss. Pearson's correlation coefficient for the profound subgroup suggested no correlation between 4FA and hearing handicap score r=-0.1(p=1.8).

Binary logistic regression analysis was to assess the relationship between educational attainment (high-school or less compared to college or greater), relevant demographic variables (income and gender) and hearing loss. The model was significant $\chi 2$ (3) =13.41, p<0.01. Those in the lower income group were 2.7 times as likely as those in the higher income group to have a high-school education or lower. No relationship between educational attainment and hearing loss category was found.

Internal consistency For those in the mild to severe hearing loss subgroup, HHI inter-item correlations ranged from 0.19 to 0.65 with all values significant ($p<0.05$). For the profound hearing loss subgroup the correlations were somewhat lower in general with several failing to show a significant correlation (item 1 failed to correlate with items; 3, 8, 9, and 10). The reliability of the HHI was assessed with Cronbach's alpha, showing $\alpha = 0.85$ for the whole population. Each hearing loss subgroup was also assessed, with the profound hearing loss subgroup showing a score of $\alpha= 0.82$ and the mild to severe group with $\alpha= 0.88$, signifying a high internal consistency (Nunnally & Bernstein, 1994). Additionally, reliability was calculated when each item was dropped, yielding an alpha coefficient ranging from $\alpha=0.79$-0.83 for the profound hearing loss subgroup and $\alpha= 0.85$-0.87 for the mild to severe hearing loss subgroup.

Subscales and Factor analysis

The correlation between the emotional and social subscales was high across the whole sample ($r=0.6$), and remained high within each of the hearing loss subgroups ($r= 0.61$ and $r= 0.59$ for the mild to severe and profound hearing loss groups respectively). Principal component analysis was applied to the HHI and revealed two factors for both subgroups (Table 3.2.). For the mild to severe group items 3, 4, 5, 8, 9 and 10 showed positive loadings to one factor; interpreted as the social subscale. This factor accounted for 34% of the variance. The second factor showed positive loadings for items 1, 2, 6, and 7; and was interpreted as the emotional subscale. The second factor accounted for 25% of the variance. The correlation between factors was found to be high at 0.70 as measured by the phi coefficient.

Table 3.2. Principle component analysis with Varimax rotation factors above 0.6 are shown in bold.

Subgroup <81dBHL

	Component	
	1	2
HC1	0.234	**0.749**
HC2	0.314	**0.705**
HC3	**0.713**	0.098
HC4	**0.771**	0.21
HC5	**0.75**	0.35
HC6	0.123	**0.78**
HC7	0.317	**0.659**
HC8	**0.646**	0.308
HC9	**0.715**	0.267
HC10	**0.715**	0.274

Subgroup ≥81dBHL

	Component	
	1	2
HC1	-0.111	**0.803**
HC2	0.142	**0.792**
HC3	**0.668**	0.027
HC4	0.38	0.5
HC5	0.362	**0.601**
HC6	0.519	0.357
HC7	0.511	0.541
HC8	**0.801**	0.011
HC9	**0.713**	0.233
HC10	**0.663**	0.268

For the profound group items 3, 8, 9, and 10 showed positive loadings to one factor, accounting for 29% of the variance. Items 1, 2, and 5 positively loaded onto a second factor, accounting for 24% of total variance. Correlation between factors was found to be high at 0.68 as measured by the phi coefficient.

Multi-linear regression analysis

Backwards, multi-linear regression analysis was performed on the whole sample as well as both subgroups to determine the relationship between the HHI total score, hearing level, and demographic variables (age, education and income). The multilinear regression analysis for the whole sample showed only monthly income to be a significant predictor of total HHI score, $R^2 = 0.06$, $F\ (1,226) = 14.4$, $p<0.001$ (Table 3.3.). The regression model was not significant and no significant predictors were found for the profoundly impaired subgroup, $R^2 = 0.03$, $F\ (5, 121) = 0.66$, $p>0.05$. Multi-linear regression results for the mild to severe hearing loss subgroup show that both income and the 4FA of the better ear were significant predictors. The final model for this subgroup explained 19% of the variance in HHI total score, $R^2 = 0.19$, $F\ (2, 104) = 11.6$, $p<0.001$ (Table 3.4.).

MANOVA

MANOVA was used to test whether the two hearing loss subgroups showed different response patterns on the HHI. Results were highly significant, $F\ (10, 298) = 4.32$, $p<0.001$; Wilk's $\Lambda = .873$, partial $\eta 2 = .13$ indicating that the groups responded differently to the test items on the questionnaires. Follow up univariate analysis suggests that the 'hearing loss subgroup' had a significant effect on the responses to questions 3 ($F\ (1,307) = 13.3$, $p<0.001$), 6 ($F\ (1,307) = 17.9$, $p<0.01$) and 9 ($F\ (1,307) = 4.9$, $p<0.05$).

Table 3.3. Backward stepwise multi-linear regression for Tagalog HHIE-S/HHIA-S scores and significant predictor variables in the whole sample.

N=226	Unstandardised Beta	Standardised Beta	Standard error	p-value	VIF
Family income per month	-4.85	-0.25	1.28	0.001	1.00

df: 1,226; F= 14.4; R^2=0.06; p<0.001

3.5 Discussion

The current study shows that a Tagalog translation of the HHI has psychometric properties similar to those described in previous research (Aiello et al., 2011; Newman et al., 1990; Ventry & Weinstein, 1983). Despite the similar psychometric profile of the translated version, the HHI appeared to be insensitive to the hearing handicap experienced by those with profound hearing loss; failing to show the expected positive relationship between hearing threshold and HHI total score when looking across the whole sample.

Previous research has concentrated on the sensitivity of the hearing handicap questionnaire in differentiating between mild, moderate and severe hearing losses. In such studies, individuals with profound hearing loss constituted less than 5% of the total study population or were not included in the study sample (Newman et al., 1990; Sindhusake et al., 2001), compared with 55.7% of the study population in the current study. Additionally, previous studies have typically reported mean 3FA hearing losses in the mild range (Gates et al., 2003; Weinstein, 1986), compared with the mean 4FA of 85.7dB in the better ear for the current study. Given that the HHI total score has previously been shown to be related to level of hearing loss (Jupiter & DiStasio, 1998), higher HHI total scores were expected and found in the current study (mean HHI total score 26.28), when compared with previous studies (mean HHI total score between 18 - 22, even in the most significantly hearing impaired groups assessed) (Newman, Jacobson, et al., 1991; Tomioka et al., 2013). Despite the high average score in the current study, the mean total HHIE-S/HHIA-S score was very similar for the profound and mild to severe subgroups. Newman et al. (1991) reports a similar finding, with mild, and moderate-to-severe groups showing similar scores on the HHIE-S.

Table 3. 4. Backward stepwise multi-linear regression for Tagalog HHIE-S/HHIA-S scores and significant predictor variables in those with 4FA <81dB

N=104	Unstandardised Beta	Standardised Beta	Standard error	p-value	VIF
4FA in the better ear	0.14	0.24	0.06	0.011	1.06
Family income per month	-6.45	-0.31	1.93	0.001	1.06

df: 2,104; F= 11.6; R^2=0.19; p<0.001

The present study showed that the HHI questionnaires have high internal reliability. Reliability was similar to that reported in the English (α= 0.87; Ventry & Weinstein, 1983), Japanese (α= 0.91; Tomioka et al., 2013) and Italian translations (α= 0.88; Monzani et al., 2007). Although it should be noted that the reliability was closer to the previous estimates when looking at the mild to severe hearing loss subgroup responses, rather than the responses from the profound hearing loss subgroup. Even when individual items were removed from the scale, Cronbach's alpha remained high, consistent with the result found in the Italian (Monzani et al., 2007) and Portuguese versions of the questionnaire (Aiello et al., 2011). This finding suggests that each item is consistently measuring aspects of hearing handicap. Inter-item correlations found in the Tagalog version of the HHI were largely similar to those found in other versions (Newman, Weinstein, et al., 1991; Ventry & Weinstein, 1983).

Principal component analysis results suggested that there are two subscales present in the questionnaire. When the analysis was performed on the profoundly impaired group, the factor loadings corresponded poorly with the emotional and social subscales suggested by the original authors. However, results from the mild to severe group showed a better, although not identical pattern to the purported subscales (Ventry & Weinstein, 1982). This finding can be explained by examining the development of the HHI. In the original development, the social and emotional subscales were validated through studies of internal reliability within subscales rather than through a factor analysis of the overall questionnaire. The present study is the first to examine the validity of the subscales of the shorted version through a factor analysis and suggests that the subscales may not be as clear/distinct as the original authors envisioned. Noble et al. (2008) report a factor analysis of the long form version of the HHI, which again suggested that the questionnaire did not clearly resolve into the two subscales intended in the development of the questionnaire. The items grouped into the two identified factors for the profound subgroup showed no easily identifiable relationship to each other, making the results hard to interpret.

Both regression and simple correlation failed to show a significant relationship between hearing thresholds and HHI score, both when evaluating the whole sample and the profoundly impaired group alone. This contrasts starkly with the literature, which has shown a clear, statistically significant relationship between hearing threshold and HHI score (Lichtenstein et al., 1988; Tomioka et al., 2013; Ventry & Weinstein, 1982). However, for participants with a mild to severe hearing loss, both simple correlation and regression suggested a moderate, statistically significantly relationship between hearing loss and HHI total score, in line with previous literature (Gates et al., 2003; Newman et al., 1990; Sindhusake et al., 2001). It was not only the relationship between hearing loss and HHI score that between the hearing loss subgroups; the results of the MANOVA suggest that the groups differed in the pattern of responses across questions within the HHI. The variability and seemingly counter-intuitive results of the profoundly impaired participants in this study suggest that the HHI was not sensitive enough to capture the handicap or reduction in health-related quality of life experienced by this group as a consequence of their hearing loss.

The HHI responses of the profound hearing loss subgroup can be explained in a number of ways. Firstly, it seems likely that there were a significant percentage of participants with a profound congenital or early onset hearing loss, many of whom may have received little or no rehabilitation due to their low SES. For these individuals, the self-evaluations of the social and emotional impact caused by the hearing loss may be biased by the fact that they have never experienced anything other than their current state of poor hearing/social and emotional impairment. Secondly, it is possible that some of the younger adults with profound hearing loss may have some experience with formal or informal sign language. Although the effect of experience with manual communication on hearing handicap has not been reported in the literature, it is possible that it could reduce the relevance of HHI questions and thus alter response patterns and scores. Unfortunately, no specific questions were included in the current study to investigate mode of communication.

Participant family income, an indicator of socio-economic status, was negatively correlated with HHI score in the whole sample and the mild to severely impaired subgroup, indicating that an increase in income is associated with a decreased score on the questionnaire (less perceived handicap from hearing loss). Whilst the literature reports a strong and relatively consistent relationship between SES and objective measures of hearing loss (Cruickshanks et al., 1998; Kubba et al., 2004) less attention has been paid to the effect of SES on self-reporting of hearing handicap. Benova et al. (2014) suggest a relationship between SES and self-report of hearing loss in a sample of older adults, however do not control for measured hearing threshold, that is, it is possible that those with higher SES are less likely to report hearing loss because they have better hearing thresholds. To our knowledge, the current study is the only study to disambiguate the link between SES and self-report of hearing handicap, showing that, when controlling for hearing threshold, those with higher SES are less likely to self-report hearing handicap. The ICF model helps to explain this finding, suggesting that contextual factors (such as income/SES) and personal factors may mediate the impact of a health condition (such as hearing loss) (World Health Organization, 2001).

The sample in this study was recruited from those attending a hearing aid donation program in Manila, it is not therefore intended to be representative of those with hearing loss in the Philippines. The high proportion of lower SES and profound impairment seen in the sample is largely explained by the donation context of the program, with those of lower SES and more hearing impaired, more likely to be recruited and fitted by the donation team. As indicated in Chapter 2, page 43, it is also possible that the sample characteristics at least partly reflect a true population difference in the proportion of more severe to profound hearing losses. No investigation of the literacy of participants were made in the present study. Future research should consider the possible impact of literacy rates where self-report data is being obtained. The use of a pilot study to investigate literacy rates in the study population, or alternative delivery methods for questionnaire material may reduce the possible impact of this potentially confounding variable.

3.6 Conclusion

Although the Tagalog HHIE-S and HHIA-S showed high internal reliability and correlations, comparable to other studies, the findings from the principal component analysis suggest that the items included in the original HHI emotional and social subscales may not be as clearly delineated as supposed. Further study with a larger population in the original English version may help to resolve this disparity.

The questionnaires' apparent lack of sensitivity to hearing handicap in individuals with a profound hearing loss needs further investigation. If repeatable, this has implications for assessing the health-related quality of life deficits caused by hearing loss in such populations, and may limit the questionnaires utility in assessing changes in outcomes following intervention. This may be particularly problematic in areas where the prevalence of severe to profound hearing loss is high, such as in LMIC.

3.7 Acknowledgements

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Declaration of interest

The authors report no declarations of interest.

Chapter 4 - Evaluation of a hearing aid donation program in the Philippines Part I: IOI-HA outcomes.

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Abbreviations: Behind the ear (BTE), Hearing Aid (HA), International Outcomes Inventory for Hearing Aids (IOI-HA), Pure-tone audiometry (PTA), Real Ear Measures (REMs), Socioeconomic status (SES), University of Santo Tomas (UST), World Health Organization (WHO).

4.1 Abstract

Objective: This study aims to evaluate the self-reported outcomes of participants attending ahearing aid donation program in the Philippines using a Filipino (Tagalog) version of the International Outcome Inventory for Hearing Aids (IOI-HA).

Design: A Filipino (Tagalog) translation of the IOI-HA was developed, evaluated and administered to a group of hearing aid (HA) users whom had previously been fitted through a HA donation program. Results of the IOI-HA were subsequently compared outcomes reported in international studies.

Study Sample: 153 participants fitted with analogue hearing aids through a 3 day HA donation program conducted in 2012.

Results: Mean scores for individual IOI-HA items ranged from 3.5 to 4.2. The results are comparable with previous reports in all domains except Usage. Usage showed lower scores than most previous studies. The correlation and factor analysis are very similar to previous studies. Greater educational attainment was linked to greater awareness of the participation restriction and impact on others caused by the hearing loss.

Conclusions:

The psychometric properties of the Filipino translation of the International Outcome Inventory for Hearing Aids were similar to those reported in previous international studies. Self-reported outcomes of those fitted in a hearing aid donation program, although similar to those fitted in a non-donation context, showed some subtle differences, highlight potential weaknesses in the donation program evaluated.

4.2 Introduction

The prevalence of disabling hearing loss in older adults and children increases exponentially as average gross national income (GNI) per capita decreases, and is highest in South Asia, Asia Pacific and Sub-Saharan Africa (World Health Organization, 2013b). While non-communicable diseases, such as hearing loss, remain prevalent worldwide, health care systems in poorly resourced developing countries typically focus on acute care and management of infectious disease and childhood survival (Beaglehole et al., 2011). In such cases, hearing health care is not considered a priority area, and many low income countries have less than 10 hearing health care professionals, including Ear, Nose and Throat surgeons or audiologists, per million persons (Goulios & Patuzzi, 2008). In such cases, philanthropic donations of hearing aids and services are a relatively common method of delivering hearing services, yet little consideration has been given to evaluating the outcomes of such programs, other than reports of numbers of hearing aids fitted/ individuals fitted (Clark, 2013).

Presumably, one reason for the lack of outcome assessment in the developing world is the lack of appropriate outcome measures. In many English speaking developed countries, a vast number of well-researched and standardized outcome measurement tools exist to assess the outcomes of audiological rehabilitation (see Dillon, 2012 for review). In non-English speaking, well developed countries, a small number of culturally specific outcomes measures have been developed (Bertoli et al., 2009), however, in many instances, direct translations of English questionnaires are used which lack cultural specificity and may render them poor indicators of rehabilitation. On the other hand, in developing countries, there are few well-validated measures for assessing the outcomes of audiological rehabilitation. The lack of valid outcome measures makes efficacious service delivery in these regions highly problematic (Tucci, Merson, & Wilson, 2010).

Cox et al. (2000) developed and subsequently investigated the psychometric properties of the intended universal outcome measure; the International Outcome Inventory for Hearing Aids (IOI-HA) (Cox & Alexander, 2002). The test was purposefully designed to have only a small number of items covering a core set of outcome variables which were considered to be internationally relevant and applicable. The authors identified seven items, assessing; hours of use, benefit, residual activity limitation, satisfaction, residual participation restriction, impact on others, and quality of life. These are rated using a five point response scale, with lower scores indicating a poorer outcome and higher scores a better outcome. Scores for each item can be summed to give a total outcome measurement (Cox & Alexander, 2002). Although the IOI-HA was envisioned to be used as part of a wider test battery assessing rehabilitation outcomes, it has been utilised as a primary outcome measure in a range of studies (Liu et al., 2011; Mustafa, 2005; Olusanya, 2004; Pienaar et al., 2010).

The IOI-HA has been translated and utilised in a number of languages (Borg et al., 2012; Brännström & Wennerström, 2010; Cox, Stephens, & Kramer, 2002; Liu et al., 2011; Mustafa, 2005) although thorough investigation of its psychometric properties have only been conducted on English (Cox & Alexander, 2002; Smith, Noe, & Alexander, 2009; Stephens, 2002), Swedish (Brännström & Wennerström, 2010; Öberg, Lunner, & Andersson, 2007), Dutch (Kramer, Goverts, Dreschler, Boymans, & Festen, 2002), and Portuguese (Gasparin, Menegotto, & Cunha, 2010) translations. Investigations of the psychometric properties of the IOI-HA suggest that it is not a uni-dimensional metric; that is, the questions may not all be measuring the same underlying construct. Investigations have generally delineated two important factors or item groups; one group of items seems to be focussed on what Cox and Alexander (2002) have interpreted as "interaction", suggesting that this group of questions relate to use of the hearing aids in relation to the real-world. Others have termed this factor "composite benefit" (Dillon, 2006) as the items generally reflect the individual's positive experience with hearing aids. The second factor usually includes items which Cox and Alexander (2002) have interpreted as relating to the individual's "introspection" about their experience with the hearing aids. Another interpretation is that these items are worded in a negative fashion and may be envisioned as a measure of "composite difficulty" (Dillon, 2006) which persists with the use of hearing aids. Psychometric investigations also typically suggest high test-retest reliability (Smith et al., 2009) and relatively high validity on the IOI-HA (Stephens, 2002).

Arlinger (2000) notes the importance of the development of internationally equivalent hearing related outcome measures and the pitfalls of assuming that a good linguistic translation of an outcome measure will lead to equivalence. Indeed Beaton et al. (2000) and others (Wild et al., 2005) have noted that to ensure content validity, a cultural adaptation may also be necessary. Further, it is suggested that after a translation and adaptation is made, the psychometric properties of the measure should be investigated to ensure that reliability, factor loadings, and other psychometric properties remain the same in the translated and adapted version (Beaton et al., 2000).

Outcomes as measured on the IOI-HA have generally been studied in the developed world with digital hearing aids; sometimes in a private/user pays context (Cox, Alexander, & Beyer, 2003), and sometimes in a partly or fully subsidised context (Smith et al., 2009). IOI-HA outcomes have been studied in the developing world context; with digital hearing aids in a user pays context (Liu et al., 2011; Olusanya, 2004; Pienaar et al., 2010), with both digital and analogue hearing aids (Magni, Freiberger, & Tonn, 2005) or with non-standard devices

(Parving, Christensen, Nielsen, & Konrádsson, 2005). Findings have generally been comparable to those in developed world contexts. In the aforementioned studies, hearing aids were generally fitted in a standard clinical manner or context, and in many cases to prescription targets using real ear measurements (REM).

The present study aim was to report on the outcomes of a large scale hearing aid donation program, with a non-standard delivery model (i.e., lack of real ear or coupler verification, simplified fitting procedure, and group setting), and with basic analogue behind-the-ear (BTE) hearing aids. It was hypothesised that the context, delivery and technology utilised would negatively impact on the self-reported outcomes of participants. A discussion of the psychometric properties of the Filipino version of the IOI-HA, and of the overall outcomes of the group are presented in relation to previous studies.

4.3 Methods

Study Design

The current study investigated the self-reported outcomes of a group of individuals fitted approximately 6 months previously in a large hearing aid donation program. Further description of the donation program follows to provide context for the study. The donation program was undertaken in Manila, Philippines by a philanthropic organization linked to a hearing aid manufacturer with the assistance of the University of Santo Tomas (UST); 749 individuals were fitted during this three-day program. Individuals were recruited for the donation program by UST, and other hearing related organizations in the Manila region via advertisement and from existing databases. The majority of the individuals had no history of amplification. Prior to hearing aid fitting, individuals involved in the donation program completed four frequency air conduction audiometry (500, 1000, 2000 and 4000Hz) performed in quiet or sound treated rooms, and ear impressions were taken by UST personnel or other partner organizations.

Each individuals hearing aid fittings were carried out in a single day with individuals moving through a series of 6 stations; registration, otoscopic/ear screening (to ensure wax and infection were not present), ear management (for treatment or advice in those with wax occlusion or middle ear conditions), fitting (see below for details), batteries (3 months supply of batteries were dispensed), and checkout (to ensure moulds were fitted correctly and patient data was collected). The fitting station was staffed primarily by representatives from the philanthropic organization.

The hearing devices fitted ranged from low to high power analogue device all of which contained a volume control, but generally no frequency response adjustment (models included the former United Kingdom National Health Service models BE18, BE19, BE34, BE52, BE54, BE105, and the Oticon GB10). The fitting protocol during the donation program involved fitting the lowest power aid available, increasing the volume control until the participant reported that an adequate but comfortable fit was achieved; if more gain was needed the next most powerful device was selected and the process repeated. Fittings were bilateral in most cases, unilateral fittings were preferred only in those cases in whom bilateral fitting was not practicable (i.e. atresia, dead ears, chronic suppurative otitis media). Although impressions were taken prior to the fitting date, the philanthropic organization did not supply custom earmoulds to the majority of the hearing aid recipients, instead, it appeared that groups of standard sized earmoulds had been constructed and the patients' ear impression was used to select an appropriate standard sized mould to fit.

Self-reported outcomes on the IOI-HA were compared to outcomes reported in other international studies. A single set of results from the developed world is provided for comparison (Cox & Alexander, 2002), the other outcomes studies are from the developing world, including; South Africa (Pienaar et al., 2010), Nigeria (Olusanya, 2004), China (Liu et al., 2011), Egypt (Mustafa, 2005), and Brazil (Gasparin et al., 2010).

Participants

A database of the 749 individuals fitted during the above mentioned hearing aid donation program was held by the University of Santo Tomas (UST). The inclusion criteria for the study included: 1) participants 18 years or older who agreed to informed consent, 2) participants who received 1 or 2 HAs as part of the donation program, and 3) participants who were able to complete the self-report outcome measure. Of the 749 adults supplied with hearing aids only 472 had adequate contact details. All participants with adequate contact details were contacted and, of those, 284 agreed to participate. However, due to a series of typhoons and tropical storms in the region many withdrew, and the number of participants dropped to 153, a response rate of 32%. Demographic details of the participants are presented in Table 4.1., which shows that the majority were of low socioeconomic status. For comparative purposes the poverty line for monthly family income has been established at 7821 pesos (Balamban, Addawe, & Darunday, 2013), meaning that most of the participants in the present study were living below the poverty line.

Table 4.1. Demographic Details of Participants

Demographic Characteristic		Percentage (%)
Gender	Male	48.4
	Female	51.6
Monthly Family Income	<10000 Pesos	77.8
	>10001 Pesos	22.2
Schooling	No Tertiary or vocational	62.9
	Tertiary or vocational	37.1
Age Category (years)	18-25	14.4
	26-40	12.4
	41-60	32.7
	>61	40.5
Tympanometry	A/Ad/As	54.8
	C	1
	B (normal or reduced ECV)	14.1
	Perforation (enlarged ECV)	12.7
	Could not test	17.3
Otoscopy	Normal/Clear	69.8
	Wax (>80%)	4
	Perforation	21.6
	Infection	4.6

Average hearing thresholds of all participants are presented in Figure 4.1. Comparative hearing and demographic data on non-respondents were not available for comparison. Unilateral hearing aids had been supplied to 24 participants (16%) and binaural hearing aids to 129 (84%). Otoscopic and tympanometric results are summarized in Table 4.1. Participants were considered to have abnormal middle ear function if they had either abnormal tympanometric or abnormal otoscopy results. Tympanometric results were considered abnormal if they suggested; significantly reduced static admittance (< 0.1 mmho) with or without enlarged ear canal volume, or negative (>-100 daPa) peak pressure. Otoscopy was conducted by an audiologist, results were considered abnormal if they indicated perforation, wax occlusion >80%, fluid behind the eardrum, discharge in the ear canal, or active infection. Abnormal middle ears were found in 58 participants (50% of those with test results).

This study was approved by the Faculty of Medicine and Surgery at the University of Santo Tomas and the Macquarie University Human Research Ethics Committee.

Assessments and Questionnaire

Otoscopy, tympanometry and pure tone audiometry were conducted in acoustically treated rooms with calibrated equipment. The English version of the IOI-HA (Cox & Alexander, 2002) was translated into Filipino (Tagalog) by a bilingual audiologist (native Tagalog speaker). This translation was then evaluated by a bilingual Audiologist at UST, potentially problematic translations were highlighted and modified after consultation with the first author. The questionnaire was presented in both Tagalog and English (see Appendix C) due to the high percentage of bilingualism in the population (approximately 75% of the Filipino population report that they can read English)(Social Weather Stations, 2008). Despite the deliberate simplicity of the language used in the IOI-HA, literacy has been a noted as a limitation of the traditional pencil and paper mode of delivery, therefore this was controlled

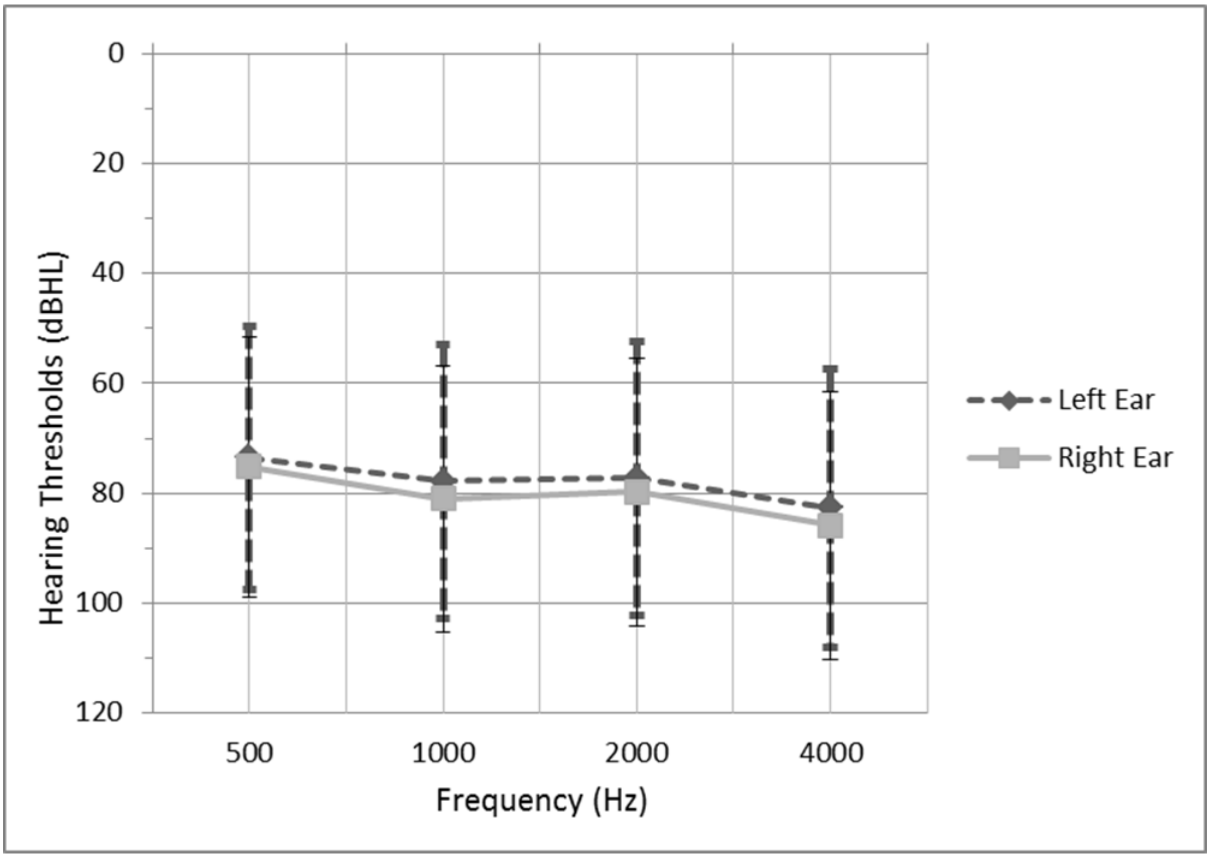

Figure 4.1. Average air conduction, pure tone audiometric results for the sample.

for by the availability of a bilingual translator/interviewer when required, verbal translation was needed in only a handful of cases.

Procedures

Prior to commencing the study, a UST staff member administered an information and consent sheet informing participants of the study aim; to assess the self-reported outcomes of the hearing aid donation program. Participants completed otoscopy, tympanometry and four frequency air conduction audiometry prior to completing the IOI-HA questionnaire in person at the UST clinic with literacy/language support available when needed. A variety of other questionnaires and objective measures were also undertaken with participants, these measures and their relationship to the IOI-HA scores will be discussed in a subsequent paper.

Data Analysis

All demographic and questionnaire data was manually entered into an Excel form. Statistical analysis was undertaken with IBM© SPSS© Statistics Package version 21 for windows (IBM Corp, 2012), only those with complete IOI-HA questionnaire data were included in the study, in the rare cases when demographic data was missing or incomplete, these participants' data were excluded from the relevant analysis. Descriptive statistics were conducted; the mean IOI-HA outcomes in this study were compared with those from other similar studies. Correlations between IOI-HA test items were investigated using Spearman's rank correlation coefficient (rho). A principal components factor analysis using varimax rotation was used to investigate the strong associations found during correlational analysis. The internal consistency (Cronbach's alpha) was determined for the test as a whole and separately for the factors identified in the factor analysis. Multivariate analysis of variance (MANOVA) with Bonferroni adjustment for multiple follow-up comparisons was used to investigate the effect of gender, education level (tertiary compared to high school or primary only), age group, and hearing loss category (mild to moderate compared to severe to profound) across the various subscales of the IOI-HA.

4.4 Results

The scales of the IOI-HA range from 1 to 5, with higher scores indicating better outcomes than low scores. The distribution of responses for each of the 7 items on the IOI-HA are presented in Figure 4.2. Figure 4.3. shows the average score for each test item in the present study. Comparative data from a number of international studies are also shown in figure 4.3. In the current study average scores ranged between 3.5 and 4.2 points on a 5 point scale. The most frequent outcome of IOI-HA Items 2, 6 and 4 was as score of 5 (the best outcome), for items 3, 5 and 7 the most frequent outcome was a score of 4 (second best outcome). Lastly for IOI-HA item 1 ("Usage") the most frequent score was a 3 (middle outcome).

The reliability of the IOI-HA as a whole ($\alpha = 0.78$; Cronbach's alpha), given the small number of items (7), suggest that the test items have acceptable to good internal consistency reliability. Correlations between items (Table 4.2.) indicate all values to be positive with many significant correlations. Factor analysis was also undertaken; all factors with eigenvalues less than 1 were dropped, leaving two factors which accounted for 66.7% of the total variance. Orthogonal (varimax) rotation was undertaken to more clearly identify the importance of items within each factor (Table 4.3.). Factor 1 explained 45% of the total variance and consisted of 5 adequate to strongly loaded items (all above .60 loading), these consisted of IOI-HA items: 1, 2, 3, 4 and 7. Factor 2 explained 21.6% of the total variance and consisted of only 2 strongly loaded items, IOI-HA items; 5 and 6. Cronbach's alpha was again calculated, this time for each factor; factor one showed an alpha of 0.84, factor 2 of 0.65 suggesting good and acceptable internal consistency respectively.

MANOVA suggests no overall relationship existed between IOI-HA responses and age, gender, and educational attainment. Although the overall model for education level was not significant, follow up univariate analysis did suggest a significant difference between educational attainment and the IOI-HA items examining residual participation restrictions $F(1,151) = 5.961$, $p<0.05$, and impact on others $F(1,151) = 4.824$, $p>0.05$. The direction of the relationship suggests increased participation restrictions and increased impact in those with higher education. Although significant, the results of this analysis should be viewed with caution and are presented only as possible areas for future investigation.

MANOVA showed no significant difference on IOI-HA outcomes for those with and without middle ear conditions in the aided ear, $F(7,108) = 1.33$, $p>0.05$. There was a statistically significant difference (MANOVA) however on overall IOI-HA responses for those with mild to moderate hearing loss when compared to those with severe to profound hearing loss $F(7,145) = 3.152$, $p<0.005$, Wilk's $\Lambda = 0.868$. Follow up univariate analysis showed that hearing loss category had an effect only on the usage item of the IOI-HA ($F(1, 151) = 6.193$, $p<0.05$), suggesting that those with severe to profound hearing loss had greater overall usage rates than those with less significant losses.

4.5 Discussion

This paper represents the first report on the outcomes of a large scale hearing aid donation program that the authors are aware of. Average outcomes on a Filipino translation of the IOI-HA in the study population were close to those reported in other developed world (Brännström & Wennerström, 2010; Cox & Alexander, 2002) and developing world

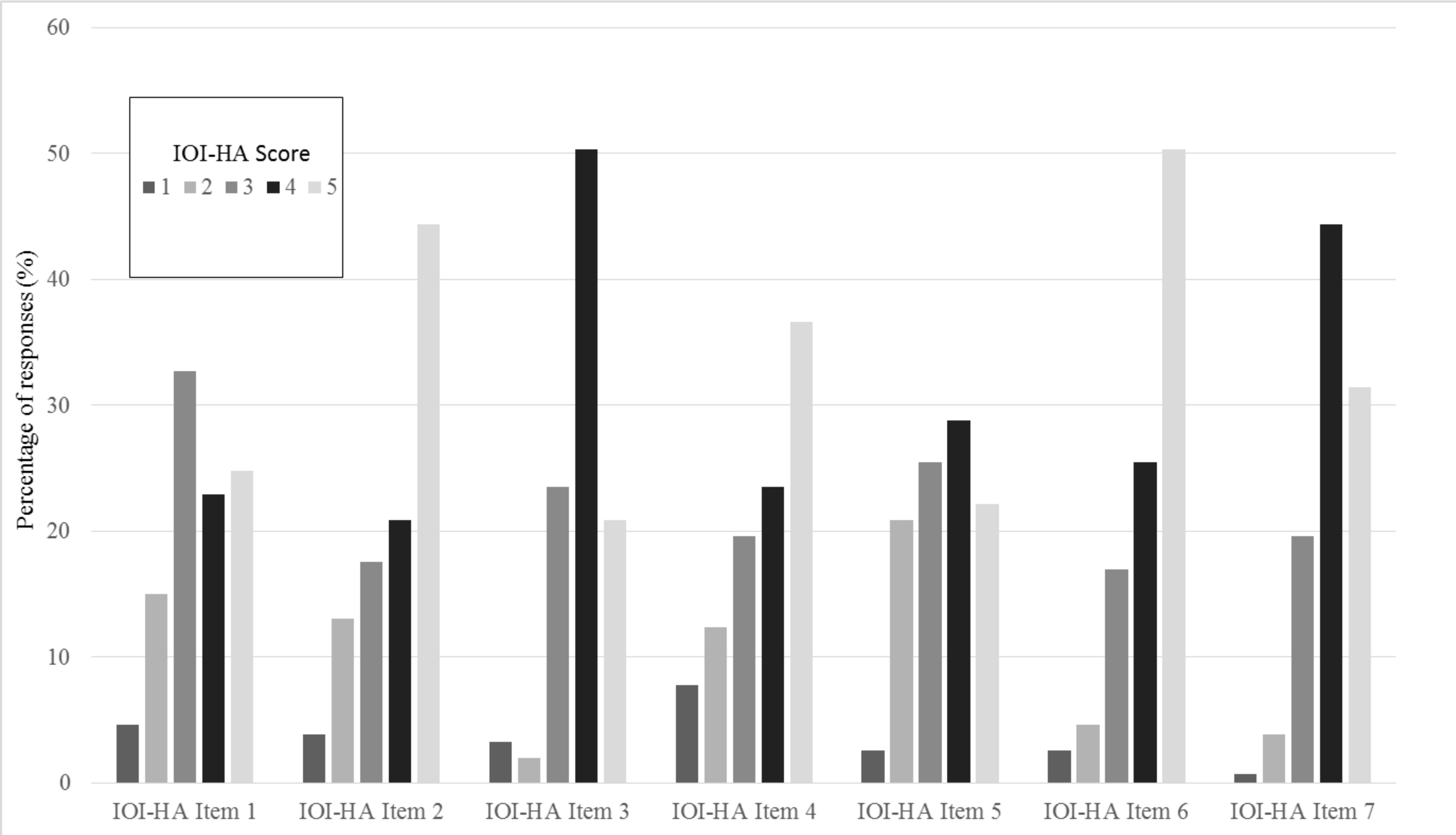

Figure 4.2. Percentage of responses by IOI-HA score for each IOI-HA question.

(Gasparin et al., 2010; Liu et al., 2011; Olusanya, 2004) studies. It is unsurprising that many of the previous studies in the developing world have shown results equivalent to those in the developed world given that, although the population was sometimes of lower socioeconomic status (SES), in most cases the service delivery method and type of devices dispensed were equivalent, or closely equivalent to those delivered in the developed world. Conversely, the population in the present study, were not only predominantly of lower SES, but were fitted with what might be considered dated technology hearing devices that were fitted using a non-standard and sub-optimal fitting protocol.

Inter-item correlations were similar to those found in previous studies (Cox & Alexander, 2002; Olusanya, 2004; Stephens, 2002). Factor analyses previously identified two factors within the English-version of the IOI-HA questionnaire; one relating to difficulty hearing with the device, and one to the benefit of wearing the device. Two factors were identified within the Tagalog version of the IOI-HA in the present study; both were similar to those emerging in previous investigations. Previous studies have shown variations in the loading of item 3. Item 3 relates to residual activity limitation and more typically loads with the composite difficulty factor (Brännström & Wennerström, 2010; Cox & Alexander, 2002; Kramer et al., 2002; Öberg et al., 2007). In the present study it appears to strongly load on the composite benefit factor. Heuermann, Kinkel and Tchorz (2005) and Stephens (2002) showed a somewhat similar pattern of factor loading for item 3. The reasons underlying the variability in factor loading are not clear, but it is unlikely to relate to translation issues, as both patterns of factor loading have been seen in the original English version.

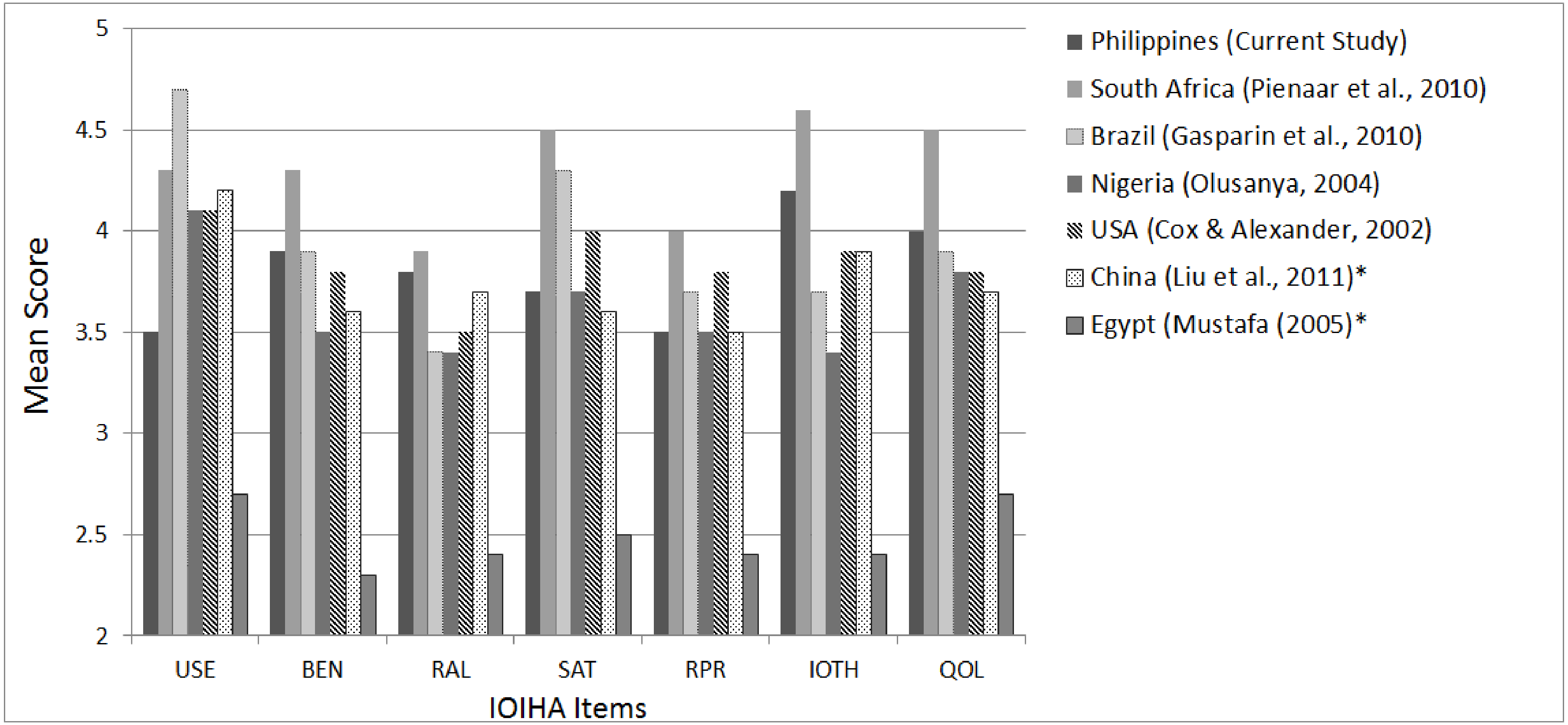

Figure 4.3. Comparison of mean IOI-HA question scores for the current and previously reported studies. * Data estimated from figures.

Mustafa (2005) reported the IOI-HA outcomes for a group with very low SES, fitted with basic analogue devices, similar to the current study population and device standard. Unlike the present study, average IOI-HA outcomes in Mustafa's study were very poor when compared to results obtained in all other reported studies. Mustafa (2005) identified a number of possible reasons for the relatively poor outcomes in the study population including; low SES, literacy rates, problems with oral translation due to regional dialects, predominantly monaural amplification, type of hearing device, and stigma-related cultural influences on satisfaction. It is not clear why participants in the present study did not report similarly reduced IOI-HA outcomes, given that they share a number of characteristics with the population reported by Mustafa (2005) such as; low SES, poor quality hearing device, and possible translation issues. The average hearing thresholds of participants were not reported in Mustafa's (2005) study, differences in average threshold could help explain some of the variation in results.

Participants in the present study were, on average, more severely hearing impaired than in most other studies reviewed (Brännström & Wennerström, 2010; Cox & Alexander, 2002; Kramer et al., 2002; Liu et al., 2011; Öberg et al., 2007; Stephens, 2002). Previous research suggests that IOI-HA outcomes do not vary greatly with hearing loss severity, with the exception of the "Usage" category, with greater levels of hearing impairment typically found to correlate with increased hours of usage. The results reported in the present study follow the same pattern of increased usage with increasing hearing loss. However, it is interesting that the participants in the present study reported, on average, lower usage than in most previous studies. Related to this, the spread of responses on the "Usage" item deviated from that seen in other studies; with a mode of 3, or "1-4 hours usage per day", compared to "More than 8

Table 4.2. Spearman's rho inter-item correlations for the Filipino (Tagalog) IOI-HA.

Correlations

		IOIHA2 Activity Benefit	IOIHA3 Residual activity limitations	IOIHA4 Satisfaction	IOIHA5 Residual Participation Restriction	IOIHA6 Impact on Others	IOIHA7 Quality of Life
Spearman's rho	IOIHA Usage Data	.436**	.241**	.389**	.027	.079	.369**
	IOIHA2 Activity Benefit	-	.477**	.720**	.164*	.249**	.626**
	IOIHA3 Residual activity limitations	-	-	.518**	.102	.157	.474**
	IOIHA4 Satisfaction	-	-	-	.067	.221**	.660**
	IOIHA5 Residual Participation Restriction	-	-	-	-	.426**	.060
	IOIHA6 Impact on Others	-	-	-	-	-	.122

hours a day" (best outcome) in most comparison studies (Brännström & Wennerström, 2010; Cox & Alexander, 2002; Kramer et al., 2002).

That educational level may be linked to the participant's awareness of residual disability and the impact of their hearing impairment on others in the current study was an interesting finding. This suggests that individuals with a higher level of education may be better able to judge the impact of the hearing loss on both themselves and others. This finding is congruent with reports from other authors, suggesting that those with higher levels of education are better able to self-judge the impact of their health condition (Mackenbach, Looman, & Van der Meer, 1996; Sen, 2002). Average education levels are poorer in the developing world than in the developed world (Barro & Lee, 1993), and are also poorer in low income groups within developing nations (Smith & Cheung, 1986). When considered in light of the results of the current study, this suggests the need to consider education when comparing self-reported hearing outcomes across cultures.

Regarding the type of hearing loss in study participants, previous research suggests poorer IOI-HA outcomes for those with sensorineural hearing loss relative to those with conductive or mixed losses (Brännström & Wennerström, 2010). In contrast, in the present study, no relationship between outer or middle ear abnormalities and IOI-HA outcomes was seen. However, because bone conduction was not performed as part of the current study, the influence of hearing loss type could not be directly accounted for. Certainly the high prevalence of middle ear conditions (Table 4.1.) suggests the need for bone conduction testing in future donation programs in the developing world where a high prevalence of middle ear disorders is already well documented (World Health Organization, 2009).

Table 4.3. Factor Loadings for Principal Component Analysis with Varimax Rotation

	Component	
	1	2
IOIHA Usage Data	**.628**	.021
IOIHA2 Activity Benefit	**.866**	.151
IOIHA3 Residual activity limitations	**.707**	.156
IOIHA4 Satisfaction	**.881**	.060
IOIHA5 Residual Participation Restriction	.004	**.874**
IOIHA6 Impact on Others	.176	**.836**
IOIHA7 Quality of Life	**.839**	.035

Note: Factor loadings over 0.6 presented in bold

In explaining the lower than expected usage rates it is important to consider both the specifications of the hearing aids utilized, and the methodology employed to fit the devices. The hearing devices used in the current study were basic analogue devices with no or very little frequency response shaping capability and only a volume control for adjustment at the fitting. Previous research is mixed, with some suggesting similar outcomes for analogue and digital devices (Bille et al., 1999; Newman & Sandridge, 1998; Parving, 2003), and some research suggesting small but significant differences in outcomes (Magni et al., 2005; Wood & Lutman, 2004). This variability, combined with the fact that more sophisticated analogue devices were used in past studies, makes it unclear whether device standard could still be a limiting factor here. The fitting protocol and user instruction provided through the donation program as previously described, was also non-standard. Best practice guidelines suggest that hearing aids should be fitted to defensible prescription targets utilising real ear measurements (British Society of Audiology and British Academy of Audiology, 2007; Valente et al., 2006). Whilst clearly there are some practical reasons not to conduct such measures in this context, lack of standardised verification could certainly have led to reduced quality of fitting and satisfaction.

One limitation of the current study relates to the translation of the IOI-HA. When utilising an existing outcome measure in a new country and in a new language it has been suggested that both translation and cultural adaptation take place (Beaton et al., 2000; Guillemin et al., 1993). The guidelines for accomplishing successful translation and adaptation (Beaton et al., 2000; Wild et al., 2005) are comprehensive, complex, and time consuming. Consequently these guidelines are often not utilised when adapting an existing hearing related outcome measure for use in a new cultural context. The present study did not conform strictly to the aforementioned guidelines and it must be acknowledged that, as such, the content validity of the resultant measure could be compromised. There was a specific attempt in the initial design of the IOI-HA to ensure a deliberately inclusive low literacy requirement level, and to keep items as general and simple as possible, with the aim of ensuring international equivalence (Cox et al., 2000). It was anticipated that the simple design would have reduced the possible problems with variations in content validity. The broad similarity of; reliability measures, factor identification, loadings, and average outcome scores may also provide some indications as to the equivalence of the translated IOI-HA used in the present study.

Limitations of the current study relating to the lack of bone conduction measures have already been discussed in detail earlier in the chapter. A further potential limitation of the current study relates to the lack of data on non-respondents in population sampled. The lack of such data means that systematic differences in the demographic characteristics or self-reported outcomes of the sample and population will be missed. This limitation should be interpreted in light of the relatively high response rate in the current study.

4.6 Conclusion

It appears that the self-reported outcomes, as measured by the Filipino translation of the IOI-HA, of individuals fitted with hearing aids in a developing world, donation context are grossly similar to those fitted in a developed world, user pays context. Some subtle but important differences, such as reduced usage rates, hint at a possible weaknesses in the donation program. It is not clear whether this weakness relates to the quality of the devices fitted or to the fashion in which services were delivered; future studies should aim to investigate this question further. The study also highlights the need to include demographic variables, such as education, when analysing self-reports of hearing rehabilitation outcome.

4.7 Acknowledgements

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Declaration of Interest

The authors report no declarations of interest

Chapter 5 - Evaluation of a hearing aid donation program in the Philippines Part II: Objective, self-reported, and performance measures

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Abbreviations: four frequency average (4FA), full on gain (FOG), hearing aid (HA), kilohertz (kHz), National Acoustic Laboratories saturation sound pressure level (NALSSPL), output sound pressure level for a 90dB input ($OSPL_{90}$), real ear measurement (REM).

5.1 Abstract

Objective: To evaluate objective outcomes of participants in a Filipino hearing aid donation program compared to self-reported outcomes.

Design: Real ear insertion gain (REIG), full on gain (FOG), output sound pressure level for a 90dB input ($OSPL_{90}$), total harmonic distortion (THD), and performance measures were made on a group of 153 analogue hearing aid (HA) users. All participants were fitted with hearing aids 6 months prior, during a large scale HA donation program, and completed the IOI-HA self-report outcome measure.

Results: Of the 282 hearing aids assessed, 61% were either non-functional >20dB from prescription target, only 1% of aids were fitted to within 6dB of prescription target across four frequencies (0.5, 1, 2, and 4kHz). IOI-HA score was not a predictor of four frequency average (4FA) fit to prescription target. Four frequency average hearing threshold and volume control preference were both significant predictors of 4FA fit to prescription target. When compared to $OSPL_{90}$ prescription targets 41% of aids were >10dB from target. Compliance with THD guidelines was poor with 50% of aids failing to meet standards at one or more frequencies. Between 54 and 78% of aids had sufficient FOG across the frequency range. Eighty three percent of the participants reported problematic feedback, 35% discomfort from the earmould, and 50% trouble inserting the earmould. Comfort in noise was associated with an 11 fold increase in the likelihood of current hearing aid usage.

Conclusions: Objective measures of hearing aid outcome were poor and showed no relationship to subjective outcome measures. The use of objective measures of outcome are indicated when evaluating hearing aid programs in the developing world.

5.2 Introduction

Hearing aids are the most commonly used device for treating sensorineural hearing loss, and in adults, are associated with improved health-related quality of life (Chisolm et al., 2007), and psychosocial and cognitive functions (Acar, Yurekli, Babademez, Karabulut, & Karasen, 2011). Despite these benefits and the high prevalence of untreated, disabling hearing loss in low and lower-middle income countries (Duthey, 2013), the WHO (2004) estimates that global production of hearing aids accounts for only 10% of the global need, with the majority of hearing aids produced being fitted in middle and high income countries. Peer reviewed studies evaluating hearing aid fittings in low and lower-middle income countries have generally taken place in a traditional clinical context, with relatively modern hearing aids fitted, in a one-on-one appointment with a clinician, and with aids validated by real ear measurement (REM)(Liu et al., 2011; Olusanya, 2004). While hearing aids fitted under such conditions appear to show outcomes similar to those of participants fitted in high income countries under similar conditions, such a clinical model is unlikely to be practical or cost-effective for the majority of individuals with hearing loss in this context and a large unmet need for hearing aids remains.

Because of the high prevalence of hearing loss (Duthey, 2013) and poor access to hearing devices in LMIC (World Health Organization, 2004), alternative methods of service delivery have also been suggested and/or adopted in these regions (ABC Tissue Hearing Express, 2015; Convery, Keidser, Dillon, & Hartley, 2011; Starkey Hearing Foundation, 2015; World Wide Hearing, 2015). One solution involves the use of large-scale donation programs that can involve large groups being fitted, and instructed on care and maintenance in the same room. Often older style analogue devices, or refurbished devices are utilised in such programs. In some cases significant efforts are made to train local health care workers or volunteers to fit or maintain devices (Pither, 2012). In many cases however, the primary focus of the program is the dispensing of hearing aids, largely carried out by overseas clinicians, who fly-in for the program but soon fly home (leading to the term fly in- fly out philanthropy). Despite the best of intentions this practice is potentially problematic as recipients are sometimes left with minimal local support, which is essential for continued success with their devices (Brouillette, 2008; Clark, 2013).

Because of a lack of published data, little information about the type of hearing aids fitted in large scale donation programs exists (Borg, 2011). It is important, however, that hearing aids should meet a set of minimum standards to ensure that they function safely, comfortably, and allow the potential for benefit within the population they are designed for. The WHO (2004) have provided a set of minimum specifications for hearing devices in low and lower-middle income countries. Amongst the general recommendations are that the hearing devices must be; easily repairable, powered by standard sized or rechargeable batteries, allow low frequency gain adjustment, and have a volume control with a 30dB range. Also provided by this document are minimum electroacoustic requirements, typically tested on a calibrated acoustic coupler, including recommendations about; output sound pressure level for a 90dB SPL input ($OSPL_{90}$), full on gain (FOG), frequency response, total harmonic distortion (THD), equivalent input noise, and battery current drain. This document also emphasises the need for appropriate custom made earmoulds, but does not provide much guidance in terms of the fitting protocol itself.

In middle and high income countries standard hearing aid dispensing involves individual assessment, fitting, and rehabilitation. A feature of some hearing aid donation programs operating in low and lower-middle income countries is group based hearing aid fittings and informational/educational counselling. A group based fitting might be considered; a group of individuals being fitted simultaneously, in the same room. There have been no reports in the literature regarding group based hearing aid fittings. There has been one randomised control trial (RCT) examining a hybrid individual/group fitting in which participants were fitted individually but received initial hearing aid orientation, education and subsequent audiological rehabilitation in a group based setting (Collins, Liu, Taylor, Souza, & Yueh, 2013). The study found no significant difference between individual and group based intervention. It should be noted that in the aforementioned study; the groups comprised only 5-6 individuals, whereas in large scale donation programs groups receiving initial counselling and instruction are typically considerably larger. It is thus not clear whether group service delivery practices, as seen in some large scale hearing aid donation programs, are effective.

Fitting protocols in some large scale donation programs in low or lower-middle income countries vary from standard clinical practice, and may be quite rudimentary, but are poorly reported in the literature. Audiological professional bodies suggest that to meet best practice guidelines hearing aid fittings should be verified using real ear measurements, with the aim of obtaining a close match to a prescriptive target (British Society of Audiology and British Academy of Audiology, 2007; Valente et al., 2006). On average, better reports of sound quality and better speech discrimination are obtained when hearing aids are fitted to target (Baumfield & Dillon, 2001; Dillon, 2012; Mueller, 2005). It is also recommended that the fitting be modified subsequent to verification based on client feedback. Minor deviations from prescriptive targets are thus not unusual even in hearing aid fittings where best practice is being followed. Large deviations however, are likely to result in poor; sound quality, speech discrimination/recognition, and if large enough, audibility. The exact tolerance figure for an adequate fit to target is not clear, but reports seems to converge on a figure of approximately +/- 6dB from target (Baumfield & Dillon, 2001; Dillon, 2012; Mueller, 2005).

Whether for-profit or not-for-profit, the outcomes of hearing aid dispensing programs in the developing world should be evaluated for quality assurance purposes (World Health Organization, 2004). Currently there are no peer-reviewed publications examining the outcomes of a hearing aid donation program. The metric often used to judge the success of a hearing aid donation program is the number of individuals fitted, as reported by those running the programs. A more comprehensive evaluation of a hearing aid donation program should consider aspects like; the technical characteristics of the hearing devices themselves, the quality of the fittings (which in turn will be partly related to quality of the hearing assessment), the quality and extent of the follow-up or support service provided, and the self-reported outcomes of those fitted in the program (World Health Organization, 2004).

In a companion study (see Chapter 4) we describe the self-reported outcomes of a group of Filipino adults fitted through a large scale hearing aid donation program, with a non-standard, group based delivery method, and with analogue behind the ear hearing aids. This study evaluates the objective and performance measures of outcome in the same population of hearing aid recipients, and compares them to the previously reported IOI-HA outcomes.

5.3 Method

Participants

The current study investigated the objective, self-reported, and performance based outcomes of a sample of individuals fitted approximately 6 months prior in a large scale hearing aid donation program. Seven hundred and forty nine individuals were fitted in a donation program spanning three consecutive days. All aids fitted though the donation program were analogue devices with a volume control but no tone control, and all were fitted in a group based “production line” like procedure. Further details of the donation program can be found in a companion paper (see Chapter 4). Of the original 749 participants, 472 provided adequate contact details and were contacted to participate in the study. Of those contacted 153 adult participants agreed to participate for the current study, a response rate of 20% of the total population fitted, or 32% of those with adequate contact details. Participants were fitted either monaurally (16%) or binaurally (84%), with 282 hearing aids/ears fitted. Participants spanned a wide age range, although predominantly in the older age group (61 years or older), with approximately even numbers of males and females recruited. Due to the donation context of the initial hearing aid program participants were predominantly of lower socioeconomic status (SES). Hearing thresholds in fitted ears were categorised according to WHO (2015) criteria with; 50% profoundly hearing impaired, 35% severely impaired, 13% moderately impaired, with the remaining 2% either falling into the slightly impaired, or no impairment category. Otoscopy and tympanometry suggested middle or outer ear pathology in approximately 50% of participants, however no bone conduction results were completed on participants. Further detailed demographic details of the participants can be found in a companion paper (see Chapter 4).

Methods and Apparatus

A self-report form was administered with a series of questions relating to; comfort in noise, mould comfort, feedback, difficulty with management, difficulty obtaining batteries, current use of the device, and attendance at follow up appointments. Volume control preference was recorded as the marked numeric value on the volume control closest to user preference. A Tagalog translation of the IOI-HA (Cox & Alexander, 2002) was also administered at this point (see Chapter 4). All participants were asked to complete a series of performance measures such as; changing the battery on the hearing aid, switching it on and off, changing the volume control and inserting and removing the aid/mould. The investigator observed and scored the success of the participant on each of these tasks.

Real ear measurement (REM) was completed with a 65dB SPL swept tone input, with the subject 1 meter from the speaker, and at 0° azimuth. The hearing aids were set at the aid users normal/preferential VC position and insertion gain (IG) figures were derived utilising the REM system software. Test box measures were made with a 2cc coupler and included; $OSPL_{90}$, full on gain, and THD. $OSPL_{90}$ and full on gain measurements were made with the VC at max, THD measurement was made with the VC at the user preference setting. All real ear and coupler measures were made on an Interacoustics Hearing aid analyser MS25.

Distance to target figures for REIG were calculated by subtracting the REIG, as measured on the real ear, from the NAL-RP (Byrne, Parkinson, & Newall, 1990) target figures. For ease of interpretation all fit to target figures are expressed as positives (i.e. whether over or under-fit values are presented in positive dB). Based on an approximate consensus from the literature (Baumfield & Dillon, 2001; Dillon, 2012; Mueller, 2005), 6dB was used as a cut off to describe whether an aid was fitted to target or not.

To provide an estimate of the ability of the hearing aids to achieve target gains, FOG was compared to the appropriate required real ear target gain. Prior to comparison coupler measured FOG figures were corrected using average, adult, real ear to coupler difference (RECD) figures (see Dillon, 2012 p. 486). FOG was subsequently subtracted from target gain, with positive values indicating that the aid had insufficient gain to achieve real ear targets.

To calculate the adequacy of $OSPL_{90}$, a difference measure was computed. Measured 3FA $OSPL_{90}$ was subtracted from the appropriate calculated 3FA NALSSPL targets (Dillon & Storey, 1998), with positive figures indicating that the aid was under target.

Procedures

Prior to completing the study a UST staff member administered an information and consent sheet. Participants completed otoscopy, tympanometry and four frequency air conduction audiometry prior to completing the; IOI-HA questionnaire, study specific questions (detailed above), and the performance measures (also detailed above). REM and coupler/test box measurements were completed following completion of the questionnaires. All measurements and questionnaires were conducted in person at the UST clinic with literacy/language support available when needed. At the completion of the study all participants were offered a follow up appointment and further instruction in the management of the hearing aid.

Data Analysis

All demographic, objective, and questionnaire data was entered manually into an Excel form. Statistical analysis was undertaken with IBM© SPSS© Statistics Package version 21 for windows (IBM Corp, 2012), in cases where demographic, questionnaire, or objective data was missing or incomplete, that participants' data was excluded from the relevant analysis. The relationship between the four-frequency average (4FA) fit-to-target and a variety of predictor variables was investigated with forward multiple regression, as was the relationship between IOI-HA outcome and a range of predictor variables. Chi-squared analysis was used to investigate the relationship between a single question regarding hearing aid usage and the IOI-HA question regarding usage (question 1.). Lastly, forward, binary logistic regression was used to identify the predictors of current usage of the hearing device.

5.4 Results

Objective measures

Sixty eight of the hearing aids (24%) were broken or non-functional and thus underwent no further testing in the coupler or patient's ear. Four aids (1.5%) had been lost and so were also not included in the subsequent analysis. Of the remaining 210 (74.5%) functioning hearing aids, REM revealed that, averaged across four frequencies, less than 4% of aids were fitted to within 6dB of the corresponding NAL-RP insertion gain targets (Figure 5.1.). Aids were fitted most closely to target at 1000Hz and most poorly to target at 4000Hz (Table 5.1.). Only 1% of aids were fitted to target at all four frequencies, ~6% were fitted to target at 3 frequencies, ~8% were fitted to target at 2 frequencies, and ~15.5% were fitted to target at 1 frequency. The vast majority of aids that failed to achieve target gains were under-fitted. In fact, of those aids >6dB from prescription target, only 4% were over-fitted, when averaged across the frequency range. Despite the general under-fitting in the sample, only 30% of participants set their volume control preferentially to the highest setting.

The relationship between the 4FA fit-to-target and a variety of predictor variables was investigated. It was found that only 4FA hearing threshold (β= -.76, $p<0.001$) and user volume control preference (β= .15, $p<0.01$) were significant predictors of fit-to-target, with the model explaining a moderate amount of the variance in 4FA fit to target figures (R^2=.52, $F(2, 179)$= 97.16, $p<0.001$). The relationship between 4FA thresholds and 4FA fit to target was negative, indicating that ears with greater levels of hearing loss were more likely to be under-fitted. Conversely a positive relationship was seen between participant preference for volume control setting and 4FA fit-to-target indicating that those with lower volume control settings were more likely to be under-fitted.

Table 5.1. Mean Electroacoustic measurements for all participants in whom the respective tests were completed*.

Electroacoustic Measurement	Mean	SD	Electroacoustic Measurement	Mean	SD
THD 500Hz	7.72 %	8.34	**IG 500Hz**	12.59 dB (Gain)	11.81
THD 800Hz	4.56 %	7.10	**IG 1000Hz**	27.29 dB (Gain)	11.60
THD 1600Hz	3.29 %	5.99	**IG 2000Hz**	21.94 dB (Gain)	10.33
$OSPL_{90}$ 500Hz	107.26 dB (SPL)	9.60	**IG 4000Hz**	11.49 dB (Gain)	10.17
$OSPL_{90}$ 1000Hz	116.83 dB (SPL)	13.93	**Distance to target 500Hz**	21.19 dB	13.91
$OSPL_{90}$ 2000Hz	112.51 dB (SPL)	11.12	**Distance to target 1000Hz**	16.61 dB	11.55
$OSPL_{90}$ 4000Hz	103.70 dB (SPL)	10.69	**Distance to target 2000Hz**	17.65 dB	10.49
FOG 500Hz	32.85 dB (Gain)	11.80	**Distance to target 4000Hz**	27.89 dB	11.97
FOG 1000Hz	45.57 dB (Gain)	11.49			
FOG 2000Hz	43.63 dB (Gain)	12.77			
FOG 4000Hz	38.98 dB (Gain)	13.59			

*Insertion gain (IG), total harmonic distortion (THD), output sound pressure level for a 90 input (OSPL90), full on gain (FOG).

Average THD and FOG figures are reported in Table 5.1. When comparing FOG measures to the gain required to meet prescriptive targets; 40% of aids at 500Hz, 28% of aids at 1000Hz, 22% of aids at 2000Hz, and 46% of aids at 4000Hz had gain inadequate to achieve prescriptive targets. The distance between the measured 3FA $OSPL_{90}$ and the prescribed NALSSPL is shown in Figure 5.2. Approximately 27% of aids were within +/- 5dB of the prescription target, with a further 32% falling within +10/-10 of the target, leaving approximately 40% more than 10dB from the prescription target, with the majority under target.

Self-reported and performance measures

Self-report questionnaire results suggest a large number of participants in the study were having practical difficulties managing their donated hearing aids (Table 5.2.), with over 40% reporting at least some difficulty with management. At least 20% of the participants had trouble obtaining/sourcing replacement batteries and over 80% reported problematic feedback. Only 35% reported that the mould provided was comfortable and only 15% reported comfort in noise. Performance measures of the participants' ability to manage the hearing aid suggested that the majority of participants were able to; change the battery, change the volume control, and switch the aid on and off, although approximately 50% had trouble inserting the earmould.

A simple self-report yes/no question asking about current usage of the hearing aid was compared to the IOI-HA question on usage. The responses on the IOI-HA questionnaire varied between the self-reported users and non-users (χ^2 (4, N = 151) = 25.165, $p < 0.005$) with current users generally reporting greater hours of usage on the IOI-HA questionnaire than non-users (Figure 5.3.).

Table 5.2. Self-Report questionnaire responses and Performance Measure outcomes.

Self-Report Questions	Percentage (%)	Performance Measures	Percentage (%)
Difficulty with management		**Able to change battery**	
Very difficult	5.9	*Yes*	89
Some difficulty	37.3	*No*	11
No difficulty	56.9		
		Able to Switch Aid on and off	
Comfort of mould		*Yes*	83
Uncomfortable	31.4	*No*	17
Adequate	32.7		
Comfortable	35.9	**Insertion of mould**	
		Could not insert	7
Comfort in noise		*Partial insertion*	43
Uncomfortable	43.4	*No problems with insertion*	50
Adequate	41.4		
Comfortable	15.1	**Able to alter volume control**	
		Yes	87
Feedback		*No*	13
Feedback	83		
No feedback	17		
Sourcing batteries			
Difficulty obtaining batteries	20.3		
No difficulty obtaining batteries	79.7		
Attended follow up appointment			
No	79.7		
Yes	20.3		
Currently wearing hearing aids			
Not wearing aids	51		
Wearing at least one aid	49		

Forward binary logistic regression was used to assess the relationship between the current use category and a range of predictor variables. Only one variable, comfort in noise, was significant in the final model (χ^2 =12.67, p<0.005 with df = 2) with only modest predictive power (Nagelkerke's R^2 = 0.169). The odds of the participant currently wearing the aid increased by 1.7 times if the comfort in noise rating was "adequate" and increased by 11 times when the comfort in noise rating was "comfortable".

Lastly, forward multiple regression was used to assess the relationship between IOI-HA total score and a range of predictor variables. In the final model, only two variables; comfort in noise (β= .33, p<0.001), and comfort of mould (β= .28, p<0.01) were shown to predicted IOI-HA scores (R^2=0.24, F(2, 120) = 18.91, p<0.001).

5.5 Discussion

The current study investigated the objective outcomes of a large-scale hearing aid donation program conducted in Manila, Philippines. The donation program dispensed hearing aids in a non-standard, group based fitting and counselling format. Objective measures of hearing aid performance indicate that the majority of hearing aids fitted as part of the hearing aid donation program evaluated were inappropriate for the population they were fitted to, largely being either underpowered or under-fitted. In total, approximately 61% of all aids fitted to participants in this study were either broken/non-functional or provided little to no functional benefit (greater than 20dB from prescription target). The finding that a significant portion of hearing aids fitted through the donation program do not meet prescription targets is noteworthy because it is likely to result in poor intelligibility and sound quality for the users of these aids (Baumfield & Dillon, 2001; Dillon, 2012; Mueller, 2005). It should also be

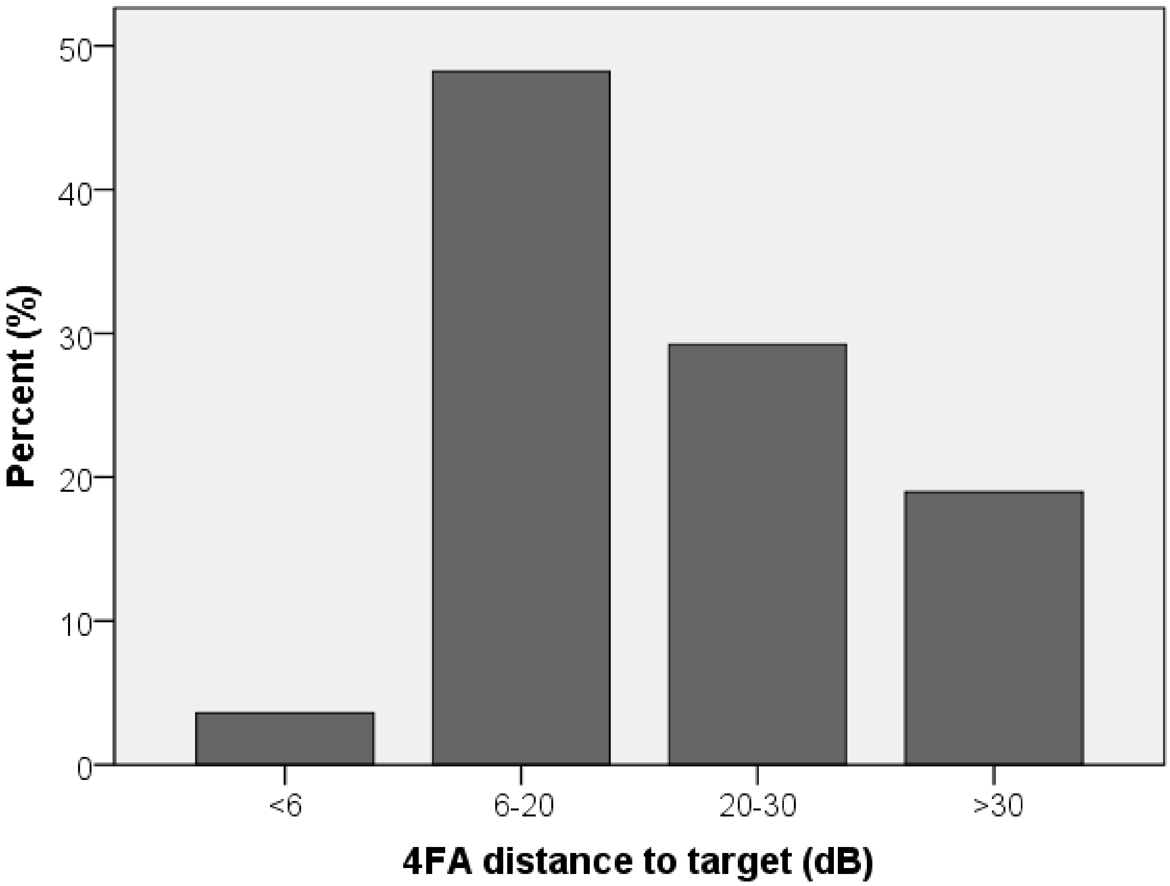

Figure 5.1. Percentage of those falling into four frequency average (4FA) distance to prescriptive target categories (expressed in positive dB).

noted that the use of REM during fitting, although best practice (British Society of Audiology and British Academy of Audiology, 2007; Valente et al., 2006) may be deemed impractical when dealing with large numbers of fittings in short time-frames. Indeed, it is not clear whether the benefits of REM hold true if the aids to be fitted are analogue, with limited control over the frequency response, and poor coupling. Indications from studies utilising aids similar to those used in the present study certainly suggest that, with the use of REM, adequate fit to target can be achieved in the vast majority of fittings (Swan & Gatehouse, 1995).

Given that assessments were taking place 6 months post-fitting there are two possible explanations for the poor average fit to target; either the aids were not fitted to target when they were dispensed, or the aids were fitted close to target, but the gain subsequently changed. In the former category, an inadequate fit could have been due to limitations of the hearing aids or the fitting methodology. In the latter category, the post-fitting variation could be due to; participants reducing the gain themselves, or to hearing aids becoming broken or damaged over the period since the fitting took place. The contribution to the poor fit target from these sources cannot be conclusively resolved here due to the design of the study, however some clues are provided by the other measures conducted and will be discussed forthwith.

The failure of the donated hearing aids to meet gain targets could be attributed to user preference, however poor FOG measures suggest a more likely cause may be inadequate reserves of gain. Although the hearing aids average FOG at 1 kHz and maximum FOG meet the suggested WHO standards (see Table 5.1.); 35% were under and 5% were over the recommended standard maximum FOG values. Additionally, FOG measures suggested that between 22 to 48% of hearing aids had gain inadequate to achieve prescriptive targets across the frequency range. Similar $OSPL_{90}$ data show that >40% of the fitted aids are not within

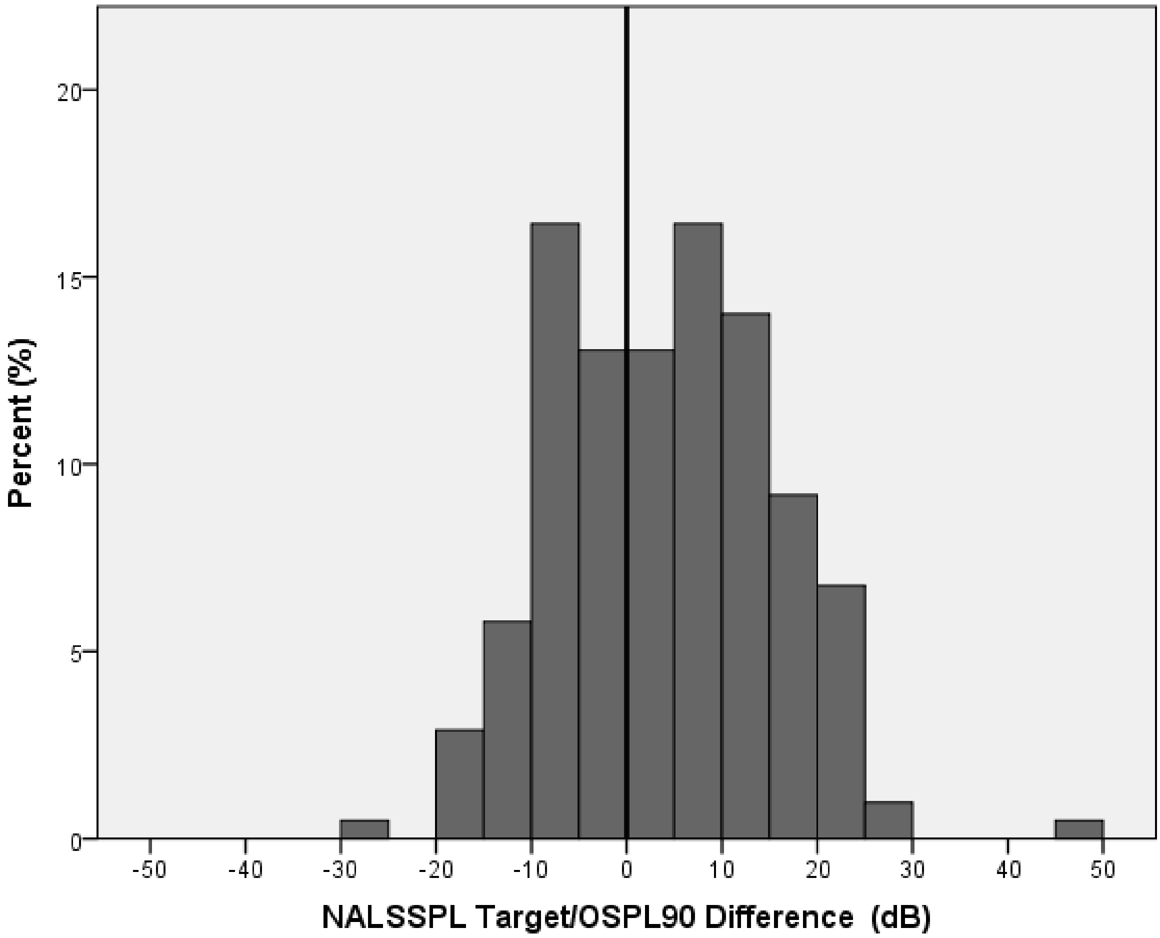

Figure 5.2. Distance between 3FA NALSSPL target and measured 3FA $OSPL_{90}$ (dB). Positive values indicate that the NALSSPL target was higher than measured $OSPL_{90}$ and vice versa.

10dB of prescriptive targets. Whilst a small number of aids (<10%) had measured $OSPL_{90}$ levels over the NALSSPL targets, indicating the potential for loudness discomfort, the majority of aids fell short of targets, which may cause distortion of conversational level speech, and in lack of audibility (Dillon & Storey, 1998). Whether the lack of gain and adequate output were a result of inappropriate aid selection or due to damage or failure of the aids subsequent to their fitting is unclear. Finally, and relatedly, average THD figures (Table 5.1.) exceeded the recommended WHO (World Health Organization, 2004) minimum specifications (5% and 2% respectively) at 500 and 1600 Hz, indeed, half of the aids exceeded the WHO THD recommendations at, at least one frequency. This suggests that a substantial proportion of the participants, regardless of the adequacy of their gain, were receiving a distorted signal.

Fit to insertion gain prescription target was poorer as hearing loss increased, with hearing thresholds in the study population including a high percentage (50%) of participants with profound loss. It is likely that the poor fit to target was exacerbated by the high proportion of severe to profound hearing losses in the study population. The WHO (World Health Organization, 2004) recommends that adult hearing aid fittings in the developing world should prioritize those with a moderate to severe hearing loss in the better ear. This is because patients with profound hearing loss on average achieve relatively poor speech recognition (Ching, Dillon, & Byrne, 1998). Research indicates that both early (Gelfand & Silman, 1993; Yoshinaga-Itano, Sedey, Coulter, & Mehl, 1998) and late (Silman, Gelfand, & Silverman, 1984) onset auditory deprivation can negatively affect the later aided outcomes of those with severe to profound hearing loss. This is particularly salient as those with profound hearing loss in the developing world have often received minimal or suboptimal treatment; potentially further limiting the benefit of later intervention. Although hearing aids would be a reasonable option for some of the profoundly impaired, a signing (manual communication) program or

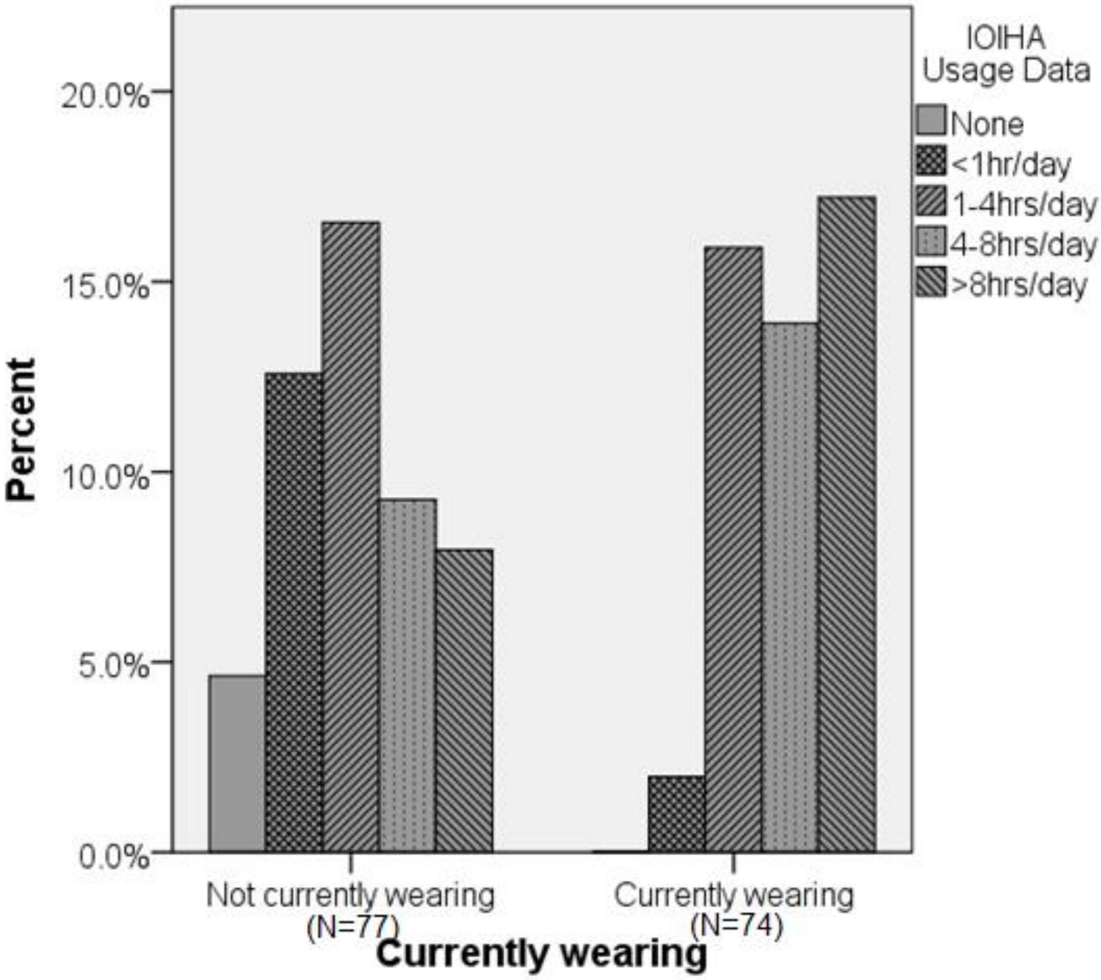

Figure 5.3. Percentage of participant responses across IOI-HA usage question category in those who report currently wearing or not wearing hearing aids.

cochlear implantation are likely to be a more suitable option for many (Zeng, 2004). However, the cost of cochlear implantation and lack of support services in the developing world mean that this strategy is often not practical (Zeng et al., 2015).

The fact that the majority of individuals in the sample were under-fitted and yet had the ability to increase the volume control setting, but did not, is intriguing. A small percentage of the patients could not operate the volume control, which may help explain this finding. It is likely that due to the relatively low $OSPL_{90}$ of the aids and relatively high gain needs of those fitted, the hearing aids would have been saturating when at higher volume control settings, possibly leading users to set the volume control to a lower level to avoid discomfort and distortion (Fortune & Preves, 1992). Saturation and distortion occur in instances such as this because the input, with sufficient gain, reaches the maximum pressure output level of the hearing aid and is peak clipped or highly compressed, altering the waveform significantly. Given the substantial number of participants (43%) reporting discomfort in noise, participants might have been utilising lower volume settings to avoid excessive noise. Limitation of gain can also be the result of audible feedback at higher gain levels (Dillon, 2012). Given that 83% of the participants in the study reported problematic feedback this could also be a factor in self-limitation of the volume control setting. Importantly feedback is partly related to the quality of the earmould, and only 30% of participants in this study reported a comfortable earmould fit. Both comfort and feedback problems could be reduced if locally made custom earmoulds were obtained in future programs, as per the WHO guidelines (2004).

Researchers and advocates have raised concerns over lack of appropriate follow up and support for those fitted with hearing aids in the developing world (Brouillette, 2008). The fact that only 20% of participants in the current study were seen for follow up, despite the poor results on the various objective outcome measures described above, appears to emphasize these concerns. Such follow-up may have resolved potential issues with inappropriate volume control setting and identified aids which were damaged/broken post fitting. Without specific provision of personnel for follow up many of those fitted will not be seen post fitting despite their need. Further, without the provision of replacement devices or repair facilities, even those whom are seen for follow-up may be left with unsuitable devices (Clark, 2013). Even for those who have functional devices, difficulties accessing follow up and support services may result in problems obtaining batteries, and managing and maintaining devices (Sooful et al., 2009). Suggestions for overcoming these problems include; the use of solar powered (Deaftronics, 2015) or rechargeable hearing aids (ABC Tissue Hearing Express, 2015), better training and utilisation of community based health workers (Sooful et al., 2009; World Health Organization, 2012a), and the use of such local workers with remote/tele-audiology support from tertiary services (Swanepoel, Koekemoer, & Clark, 2010).

In a companion paper (see Chapter 4) the self-reported outcomes of the current study's participants are documented, with the results from the Filipino (Tagalog) translation of the IOI-HA showing similar findings to other studies from both the developed and developing world (Cox & Alexander, 2002; Gasparin et al., 2010; Liu et al., 2011; Olusanya, 2004; Pienaar et al., 2010). Given these self-reported outcomes, the data showing a generally poor fit to target in the current study was unexpected. The literature does report a variety factors which have been shown to mediate subjectively measured outcomes, including; lower expectations, SES, lifetime experience with hearing aid use, and self-reported hearing problems (for a review, see Knudsen, Öberg, Nielsen, Naylor, & Kramer, 2010). Population variations in the afore mentioned factors might then be expected to produce a baseline shift in subjective outcomes. In the absence of obvious floor or ceiling effects in subjective outcome, the expected correlation between IOI-HA scores and the closeness of fit to target would still be expected to persist. Although unusual, the lack of such a correlation is not unique. For example Taylor (1993) reports a lack of relation between functional measures of benefit (functional gain) and self-reported outcomes for a group of elderly hearing aid users.

A further non-audiological factor that could relate to self-reported hearing aid outcomes is a cultural response bias. The literature suggests that participants of a Filipino background may acquiesce to questions, or respond in a more extreme manner than those from other cultural backgrounds (Harzing, 2006), although this has not been a consistent finding (Grimm & Church, 1999). Given the donation context of the hearing aid program assessed, the Filipino cultural value of “utang na loob”, which roughly translates as “debt of gratitude” might be pertinent to understanding the disparity between the objective and subjective outcome measures seen in the current study (Kaut, 1961). As such it is possible that a positive response bias was driving the self-reported outcome in the current study. Certainly this highlights the need for objective as well as subjective measures of outcome when undertaking assessments of hearing aid donation programs in the developing world.

5.6 Conclusions

Based on the objective measures of hearing aid function, the majority of participants sampled were receiving minimal benefit from their hearing aids, despite positive self-reported outcomes. The study raises a number of important points relevant to those planning and evaluating hearing aid donation programs in the developing world. Firstly, the inclusion of objective measures of hearing aid performance should be considered when evaluating program efficacy to avoid self-report bias. Further, as suggested by the WHO (World Health Organization, 2004), the population should be carefully selected; a focus on those with moderate to severe hearing loss would result in both a better fit to target, fewer issues with feedback, and better overall outcomes. What is also clear, is that efforts must be made to ensure adequate follow up is provided to those receiving devices through donation programs. The current study suggests that without such efforts, a significant number of hearing aids will be providing limited benefit at 6 months post fitting.

5.7 Acknowledgements

The authors would like to thank Mr Rohan Biddulph for the time and effort he spent collecting the data for this project. The authors would also like to thank the staff and students at the Centre for Audiological Science at the University of Santo Tomas for their assistance with the project.

Declaration of Interest

The authors report no declarations of interest

Chapter 6 - Conclusions

6.1 Brief review of framework

Broadly, this thesis has investigated hearing health in the Philippines, with the wider goal of gaining a better understanding of hearing loss, its impact, and its remediation in low and lower-middle income countries. The thesis began with the premise that reducing the impact of disability involves; reducing barriers to the access of health services, creating more efficacious rehabilitative services, and increasing research into disability (World Health Organization, 2014). A series of four papers addressed these aims by providing:

- a clearer understanding of the prevalence and impact of hearing loss in the Philippines,
- a set of standardised measures of hearing disability and hearing program outcome, translated and normed on local populations and,
- an investigation of the efficacy of a hearing aid donation program.

6.2 Key findings and contribution to the field

6.2.1 High prevalence of hearing loss and ear disease in the Philippines

Chapter 2 presents a population based study of hearing and ear disease in the Philippines address the unmet need for; peer-reviewed, published data on the prevalence of hearing loss in the Philippines. The results suggest that the prevalence of hearing loss and ear disease in the Philippines is high compared to the prevalence rates in high income countries (Agrawal et al., 2008; Cruickshanks et al., 1998; Davis, 1989; Fortnum et al., 2001; Gopinath et al., 2009; Hong et al., 2015; Moscicki et al., 1985; Paradise et al., 1997; Stevens et al., 2013; Uimonen et al., 1999; Van Naarden et al., 1999). Even when compared to the prevalence rates reported in other LMIC, both paediatric and adult hearing loss prevalence rates were amongst the highest seen in the literature (Al Khabori & Khandekar, 2004; Béria et al., 2007; Bu et al., 2011; Little et al., 1993; Mann et al., 1998; McPherson & Holborow, 1985; Mishra et al., 2011; Prasansuk, 2000; Saunders et al., 2007; Wang et al., 2010; Westerberg et al., 2005). Wax occlusion and middle ear disease were similarly at the higher end of prevalence rates reported in the literature (World Health Organization, 2009).

These results highlight the need for country or region specific prevalence data. Such data provide a platform for; advocacy for improved services for ear and hearing health, increased awareness of hearing loss and its sequelae, and improved targeting of services, with an ultimate aim of providing better access to hearing health related services for the local population (World Health Organization, 2009).

6.2.2 Higher proportions of severe and profound hearing losses in LMIC than in high income countries

In Chapter 2, for those over 55 years of age with hearing loss, there was a 3.3 fold increase in the proportion of those with severe to profound level of hearing loss in the Philippines than in an Australian population (Sindhusake et al., 2001). Although such results have not been previously reported in the literature, re-categorisation and comparison of data presented by researchers conducting a large, population based prevalence study in China (Wang et al., 2010) suggests a pattern of results similar to the data from the Philippines. As both China and the Philippines are LMIC and Australia is a high income country; it is possible that these results reflect a wider trend of disparity in the average degree of hearing loss seen in developed and developing world populations. It is not clear whether these results generalise to those less than 55 years of age as no data was available for comparison.

The importance of such a finding lies mainly in its relationship to the types of intervention offered to those with varying degrees of hearing loss. If those planning (re)habilitation are aware that they will encounter a greater proportion of more severe and profound loss;

appropriate amplification options can be prepared, alternatives to amplification can be explored and considered in the planning stages, and better targeting of specific services to population needs may be achieved. This issue is reflected in the limitations of the donation program described in Chapters 4 and 5 of this thesis. The specifics of the donation program and its limitations will be discussed in subsequent sections of this thesis, but in brief; the study sample were predominantly severely to profoundly hearing impaired, whereas the technology and delivery method utilised in the program were more appropriate for a population with a mild to moderate hearing loss.

The literature reports a relationship between the impact of hearing loss and its degree (Dalton et al., 2003; Lichtenstein et al., 1988). The findings discussed above suggest that, of those with disabling levels of hearing loss, the degree of the loss will be, on average, greater in those from LMIC. As such, simple comparisons of prevalence estimates of disabling hearing loss across countries or regions may lead to underestimates of the actual burden of disease caused by hearing loss in LMIC.

6.2.3 Limitations of self-reported measures of hearing handicap

The direct translation of well validated and normed self-report measures, from one language to another has the potential to reduce the validity of those measures (Guillemin et al., 1993). The literature across a range of health fields reports the potential danger of such simplistic assumptions of generalisability across cultures. Cultural adaptations may be necessary, and at the very least, investigation of the psychometric properties of translated measures must be undertaken to ensure validity.

Chapters 3 reports the psychometric properties a translated version of one common measure of hearing handicap, the screening versions of the HHI (Newman, Jacobson, et al., 1991; Newman, Weinstein, et al., 1991). The sample populations had audiological characteristics somewhat unique in the literature; average hearing thresholds were significantly poorer than in all previously reported studies. The unusual sample characteristics reflect both a true difference in the character of hearing loss in the population at large (as discussed previously), and also a recruitment bias in favour of the more significantly hearing impaired.

When looking across the whole sample the psychometric properties of the questionnaire broadly reflected the results of previous studies (Aiello et al., 2011; Newman et al., 1990; Ventry & Weinstein, 1983), however the expected relationship between hearing thresholds and measured hearing handicap was absent. The sample was subsequently split into two groups; a severe to profound hearing loss group, and a mild to moderate hearing loss group, and re-analysed.

The psychometric properties of the HHI questionnaire were similar to previous reports in the literature when applied to the mild to moderately hearing impaired group, but poorly reflected the literature when applied to the profoundly hearing impaired group (Aiello et al., 2011; Newman et al., 1990; Ventry & Weinstein, 1983). This study also reports the first factor analysis of the screening version of the HHI. The questions comprising the purported emotional and social subscales are well, but not perfectly substantiated by the factor analysis in the mild to moderate group, but are poorly reflected in the factor analysis on the more severely to profoundly impaired group. These results suggest that self-report measures of hearing handicap, such as the HHI, should be interpreted with caution when applied to severe to profoundly impaired populations in LMIC. It is not clear if this apparent lack of sensitivity would extend to populations of profoundly impaired adults in a high income context.

6.2.4 Limitations of hearing aid donation programs

Chapters 4 and 5 of this thesis examine a large scale hearing aid donation program run by a manufacturer aligned, not-for-profit organization, with local support. The program was successful in the sense that 749 individuals were fitted with hearing aids over just a 3 day period. The high number of fittings in such a short time was achieved through the use of a non-standard, group based fitting and counselling procedure. The hearing aid technology was also unusual (within a modern context), in that the aids fitted had only a volume control, with no control over the frequency response, and were not fitted with custom earmoulds. Although drawn from a different donation program, the sample reported in the Chapters 4 and 5 resembled the demographics and audiological characteristics of the sample reported in Chapter 3; with a high proportion of participants having a severe to profound hearing loss.

The high percentage of broken or non-functioning aids (24%) suggests limitations in the effectiveness of follow up mechanisms instituted by the donation program, and indicates that greater focus must be placed on maintenance and local resources for repair or replacement of devices in the future. Such suggestions are congruent with community based rehabilitation approaches promoted both by the WHO, and in the general literature (Finkenflügel, Wolffers, & Huijsman, 2005; World Health Organization, 2012a). Community based rehabilitation focuses on upskilling and empowering local communities to assist in the management of chronic health problems such as hearing loss, rather than reliance on centralised (or fly in-fly out) type interventions. Providing training for a small number of existing community health workers in the management of existing hearing aids (e.g. checking aids, basic repairs, establishing referral mechanisms) would be a cheap and effective way of avoiding some of the limitations of the existing donation program (Clark, 2013; World Health Organization, 2012a).

Of the remaining functional aids; only 4% were adequately fitted to prescription targets averaged across 4 frequencies, few met output sound pressure level for a 90dB input ($OSPL_{90}$) prescriptions, many exceeded total harmonic distortion (THD) guidelines, and a sizeable proportion showed FOG insufficient for the population being fitted target (Baumfield

& Dillon, 2001; Dillon, 2012; Mueller, 2005) . These results likely reflect both a weakness in the fitting procedure, and a mismatch between the hearing aids and the population to which they are being fitted.

6.2.5 Lack of congruence between subjective and objective measures of hearing aid outcome

Chapters 4 and 5 respectively report the subject and objective measures of hearing aid outcome in a sample of those receiving intervention during a large scale hearing aid donation program as described in the previous section. The subjectively reported outcomes of the hearing aid fitting, as measured by a translated version of the IOI-HA appeared very similar to those reported in a high income context. The only exception to this was a lower than expected usage rate; with the average usage rate at least half a category lower than reports from the nearest developed world study. Objectively measured outcomes (as reported in the previous section) were compared to the subjectively measured IOI-HA total score. The IOI-HA was not a significant predictor of the objectively measured closeness of fit to prescription target. This result was surprising given the literature supporting a clear link between fit to prescription target and both; objectively measured speech recognition, and subjectively reported sound quality target (Baumfield & Dillon, 2001; Dillon, 2012; Mueller, 2005; World Health Organization, 2004).

The question of why participants were reporting significant benefit from their hearing aids when they were objectively poorly fitted is difficult to conclusively answer given the design of the study. This incongruence may be largely the result of the donation context, and a resultant response bias from the participants, appreciative of the assistance they were receiving. Previous reports have indicated some variations in self-report response patterns across cultures which may have contributed to the apparently contradictory results (Beaton et al., 2000; Guillemin et al., 1993; Wild et al., 2005). Regardless of the underlying cause, these results strongly suggest the need for objectively measured outcomes to be utilised when assessing the success of hearing aid donation programs to ensure the quality of the program.

6.3 Future research

In Chapter 2 this thesis provides an estimate of hearing loss and ear disease prevalence in the Philippines, based on a randomly selected population sample. Three key weaknesses in the sample design and conduct of this study could be explored in future research. The first is the size of the sample, which in epidemiological terms, was only small to medium. A larger sample would allow greater confidence in prevalence estimates and improve the representativeness of the sample. Secondly, the demographic details of the sample population in the current study did not match the population demographics perfectly, particularly in terms of the gender ratio. Future studies should consider the data collection methodology, particularly the time at which data collection takes place, in order to ensure all household members are present during data collection. Thirdly, Chapter 3 focussed on the prevalence of disabling hearing loss, little attention was paid to mild hearing loss due to concerns about the impact of background noise during the assessment sessions. Better control over background noise levels would allow greater confidence in prevalence estimates of mild hearing impairment in future studies. The use of background noise level monitoring, portable booths, and insert earphones with headphones over the top have been used in previous studies to ensure better control of background noise (Fisher & Williams, 2013).

Popular measures of hearing handicap; the screening versions of the HHI, were translated and evaluated in Chapter 3 of this thesis. The findings reported in Chapter 3 suggest that the questionnaire had reduced sensitivity to hearing handicap when used with a severe to profoundly impaired Filipino population. Although hinted at in one previous study (Newman, Jacobson, et al., 1991), this appears to be the first study to explicitly investigate this phenomenon in the literature. Further research is required to examine whether such results are repeatable in high income countries with severe to profoundly impaired populations.

Chapters 4 and 5 present the results of a hearing aid donation program in the Philippines, limitations in the; targeting of appropriate populations, provision of follow up services, and fitting methodology were suggested. This is the first study examining the outcomes of a hearing aid donation program, hence it is not clear whether the limitations found in this program generalise to other such programs internationally. Future investigations should therefore target a wider variety of donation programs, both in the Philippines and internationally. A systematic examination of the optimal methods for fitting and supporting large numbers of hearing impaired individuals in a hearing aid donation program should also be considered.

6.4 Conclusion

To give away money is an easy matter and in any man's power. But to decide to whom to give it and how large and when, and for what purpose and how, is neither in every man's power nor an easy matter.

- *Aristotle (384 - 322 BC)*

The collective results of the papers presented in this thesis suggest that hearing loss and ear disease represent a significant burden of disease in the Philippines, and that both the prevalence of disabling hearing loss and the average degree of hearing loss may be greater than in high income populations. Hearing aid donation programs represent a key component of the current response to the alarmingly high prevalence of disabling hearing loss in the Philippines (as in many LMIC), yet little attention had been paid to the conduct and outcomes of such programs. This thesis details a number of limitations to the donation program investigated, finding that the population receiving audiological management could be better targeted, and that the technology utilised needed to be better matched to the target population. A lack of provision for follow up services was also a key limitation which could be overcome with a shift towards a community based rehabilitation model. Many of these limitations may be resolved with relatively minor changes in the planning and execution of future programs and may result in significant improvements in fit and management of donated devices.

Appendix A – Ear and Hearing Disorders Questionnaire

SCHEDULE I
Household Intake Form

THIS FORM SHOULD BE COMPLETED FOR EVERY HOUSEHOLD WITH THE HELP OF THE COMMUNITY HEALTH WORKER.

Prevalence Survey on Ear Disorders and Hearing Impairment in the Philippines

This survey is being conducted by the **University of Santo Tomas – Center for Audiological Sciences** to establish data on ear disorders and hearing impairment in the Philippines. To be utilized by public health planners, information gathered from this survey is vital in the development of culturally sensitive and scientifically acceptable practices on the prevention, management and re/habilitation of hearing impairment in the Philippines.

Your household has been randomly selected to be part of the prevalence survey that aims to establish relevant data on ear disorders and hearing impairment in the Philippines. During the process, primary member of your household will be asked to complete Schedule I, a questionnaire on your household's information while all member's of your household will be screened using an otoscope to visually inspect the ear and audiometer to measure sensitivity of hearing results as indicated on Schedule II. There is *limited risk of personal danger or discomfort* in participating in this survey. All *information and personal details obtained during this survey will be treated confidentially through coding of information collected*.

For questions or more information about the survey, you may contact **Dr. Norberto Martinez, MD** - Director UST – Center for Audiological Sciences located at Room 413, Medicine Building, University of Santo Tomas, Espana, Manila with contact numbers (02) 406 1611 Loc. 8230.

I, ____________________, have read and understand the information above and any questions I have asked have been answered to my satisfaction. I agree to participate in this survey with knowledge that I can withdraw at any time without consequence. I have been given a signed copy of this consent form to keep.

Participant' Name: ______________________________
Participant's Signature: ________________ Date: __________

Investigator: NORBERTO MARTINEZ, MD
Signature: ______________ Date: ____________

A. CENSUS

1. Country Number.................. ☐☐☐
2. Administrative Division........ ☐☐
2. Study Number...... ☐☐
3. Cluster.................. ☐☐
4. Household.............. ☐☐

B. DEMOGRAPHIC PROFILE

I. Monthly Household Income
- 0 to P5,000.00.................................. ☐
- P5,000.00 to P9,999.99......................... ☐
- P10,000.00 to P14,999.99...................... ☐
- P15,000.00 to P19,999.99...................... ☐
- P20,000.00 to P24,999.99...................... ☐
- P25,000.00 and above.......................... ☐

II. Other Living Condition
1. Housing Structure
   - Makeshift.. ☐
   - Light materials................................ ☐
   - Concrete... ☐
   - Combined heavy and light materials.. ☐
2. Sanitation Facility
   - Public sewer.................................... ☐
   - Septic tank...................................... ☐
   - Pit.. ☐
   - Excretion to environment.................. ☐
   - Others.. ☐
   - *Specify:* ____________________
3. Potable Water Supply
   - Rainwater... ☐
   - Mountain spring............................... ☐
   - Rivers and lakes............................... ☐
   - Surface well..................................... ☐
   - Deep/Artesian well........................... ☐
   - Water system.................................... ☐

III. Indicate all Members of the household

NAME	SOURCE OF INCOME
1. ____________________	☐☐
2. ____________________	☐☐
3. ____________________	☐☐
4. ____________________	☐☐
5. ____________________	☐☐
6. ____________________	☐☐
7. ____________________	☐☐
8. ____________________	☐☐
9. ____________________	☐☐
10. ____________________	☐☐

*Reference for Source of Household Income
1. Employed/Self-employed
   - a. Clerical
   - b. Agricultural
   - c. Educational
   - d. Industrial
   - e. Marketing
   - f. Retail
2. Unemployed
   - a. Food support from relatives
   - b. Backyard garden
   - c. Backyard livestock raising
   - d. Minor

SCHEDULE II

WHO/PDH Ear and Hearing Disorders Examination Form Version 7.1A

A. CENSUS

1. Country Number ☐☐☐ 2. Study Number ☐☐ 3. Admin Division ☐☐ 4. Cluster ☐☐ 5. Household ☐☐ 6. Person ☐☐ 7. Optional ☐☐

8. Name........................ 9. Age in Years ☐☐ 10. Age in Months ☐☐ 11. Male / Female ☐ 12. Exams Status ☐ 13. Date ☐☐☐☐☐☐ D D M M Y Y

B. HEARING EXAMINATION

(I) Hearing Assessment for children (Age 6 months to 3 years 11 months)

	Yes	No	Not Done
1. A child searches for the sound direction and he/she shows some response such as smile or pause when you call his/her name.	☐	☐	☐
2. A child can point to a parent or brother and sister when you ask, and can speak simple words such as "mama" or "bye bye".	☐	☐	☐
3. A child can answer your question for his/her name & can repeat sentences which you give.	☐	☐	☐
4. Child reflexly blinks to loud noise.	☐	☐	☐

(II) Audiometry (Age 4 years or over)

1. Ambient noise.................. ☐☐ dBA
2. Hearing Thresholds

Right (dBHL)		Left (dBHL)
☐☐	1KHz	☐☐
☐☐	2KHz	☐☐
☐☐	4KHz	☐☐
☐☐	1KHz	☐☐

Screening Examiner's Number .... ☐☐ Screening Examiner's Remarks:

Not fully examined in this section .... ☐

C. BASIC EAR ASSESSMENT

Mark all abnormal findings which apply

	R	L	R	L
I. Ear Pain..................	☐	☐		
II. Auricle				
1. Malformation..................	☐	☐		
2. Normal..................			☐	☐
III. External ear canal				
1. Inflammation..................	☐	☐		
2. Wax..................	☐	☐		
Removed..................	☐	☐		
3. Foreign body..................	☐	☐		
Removed..................	☐	☐		
4. Otorrhea..................	☐	☐		
Removed..................	☐	☐		
5. Fungi..................	☐	☐		
6. Normal..................			☐	☐
7. Not seen..................	☐	☐		
IV. Ear drum				
1. Perforation..................	☐	☐		
2. Dullness or Retraction..................	☐	☐		
3. Red and Bulging..................	☐	☐		
4. Normal..................			☐	☐
5. Not seen..................	☐	☐		
V. Middle Ear				
1. Otorrhea..................	☐	☐		
2. Normal..................			☐	☐
3. Not seen..................	☐	☐		
VI. Others..................	☐	☐		
Specify________				
Normal findings..................			☐	☐
Not examined..................	☐	☐		

VII. Additional information

(This question to be answered for subjects reporting deafness or hearing impairment)

- Since infancy/childhood (0 – 14y).................. ☐
- Since adulthood (15 – 59y).................. ☐
- Since old age (60y+).................. ☐
- Uncertain.................. ☐

(This question to be answered for all subjects)

Does any brother/sister/offspring/parent of subject Have difficulty hearing?

No..........	☐	Brother or sister..........	☐
Yes..........	☐	Child of subject..........	☐
Uncertain..........	☐	Parent of subject..........	☐

D. CAUSE OF EAR DISEASE AND/OR HEARING IMPAIRMENT

	R	L
Normal ear and normal hearing..................	☐	☐
I. Ear Disease		
1. Wax..................	☐	☐
2. Foreign body..................	☐	☐
3. Otitis Externa..................	☐	☐
Otitis Media		
4. Acute..................	☐	☐
5. Chronic suppurative..................	☐	☐
6. Serous (with effusion)..................	☐	☐
7. Dry perforation of Tympanic Membrane	☐	☐
8. Other..................	☐	☐
II. Infectious Diseases.................. Specify________	☐	☐
III. Genetic Conditions.................. Specify________	☐	☐
IV. Non-Infectious Conditions.................. Specify________	☐	☐
V. Undetermined Cause.................. Specify________	☐	☐

E. ACTION NEEDED

	R	L
I. No action needed..................	☐	☐
II. Action needed..................	☐	☐
1. Medication..................	☐	☐
2. Hearing aid..................	☐	☐
3. Language/speech rehabilitation..................	☐	☐
4. Special needs education..................	☐	☐
5. Vocational Training..................	☐	☐
6. Surgery Referral..................	☐	☐
Urgent..................	☐	☐
Non-urgent..................	☐	☐
7. Others..................	☐	☐
Specify________		

Special Examiner's Number

Special Examiner's Remarks:

Date of Version: 9.3.08

Version 7.1A

Appendix B – Tagalog translated HHIA-S and HHIE-S

HHIA-S AGE UP TO 65

1) Please tick either No, Sometimes or Yes for each question.
Kudlitan (√) alimansa "Hindi", "Minsan" o "Oo" angbawattanong.
2) Do not skip a question if you avoid a situation because of a hearing problem.
Kung angsitwasyon ay iyonginiiwasandahilsaiyongpandinig, sagutin pa rinangtanong.
3) If you use a hearing aid, please answer according to the way you hear with the aid.
Kung ikaw ay gumagamitng "hearing aid", sagutinangbawattanongnanaayonsaiyongpandinigkapaggamitang "hearing aid."

	No *Hindi*	Sometimes *Paminsan-minsan*	Yes *Oo*
1. Does a hearing problem cause you to feel embarrassed when you meet new people? *Nagdudulotbangkahihiyanangiyongpandinigkapagnakipagkilalakasa bagongtao?*	☐ 0	☐ 2	☐ 4
2. Does a hearing problem cause you to feel frustrated when talking to members of your family? *Nagdudulotbangkabiguanangiyongpandinigkapagikaw ay nakikipag-usapsaiyongpamilya at kamag-anak?*	☐ 0	☐ 2	☐ 4
3. Do you have difficulty hearing / understanding co-workers, clients or customers? *Nahihirapankabangmakarinig o di momaintindihanangiyongkasamahansatrabaho, kliyente o mamimili?*	☐ 0	☐ 2	☐ 4
4. Do you feel handicapped by a hearing problem? *May kapansanankabadahilsaiyongpandinig?*	☐ 0	☐ 2	☐ 4
5. Does a hearing problem cause you difficulty when visiting friends, relatives or neighbours? *Dahilsaiyongpandinig, nahihirapankabangmakipag-usapkapagbinibisitamoangmgakaibigan, kamag-anak o kapitbahay?*	☐ 0	☐ 2	☐ 4
6. Does a hearing problem cause you difficulty in the movies or in the theatre? *Dahilsaiyongpandinig, nahihirapanka bang manoodsasinehan or sadulaan?*	☐ 0	☐ 2	☐ 4
7. Does a hearing problem cause you to have arguments with family members? *Dahilsaiyongpandinig, nagkakaroonkabang di pagkakaunawaansaiyongpamilya?*	☐ 0	☐ 2	☐ 4
8. Does a hearing problem cause you difficulty when listening to TV or radio? *Dahilsaiyongpandinig, nahihirapangkabangmakarinigsatelebisyon o radio?*	☐ 0	☐ 2	☐ 4
9. Do you feel that any difficulty with your hearing limits or hampers your personal or social life? *Dahilsaiyongpandinig maylimitasyonbaangiyongpansarili or panlipunangbuhay?*	☐ 0	☐ 2	☐ 4
10. Does a hearing problem cause you difficulty when in a restaurant with relatives or friends? *Dahilsaiyongpandinigmahirap bang makarinigkapagikaw ay nasakarinderyakasamaangmgakamag-anak o kaibigan?*	☐ 0	☐ 2	☐ 4
Totals:			

11. Do you feel that you need a hearing aid? *Sa palagaymo, kailanganmobaang "hearing aid"?*

☐No/*Hindi* ☐Maybe/*Marahil* ☐Yes/*Oo*

12. How confident are you in your ability to manage/use a hearing aid? *Gaanokapalagayangiyongloobsaiyongkakayahanggamitinang "hearing aid"?*

☐Not at all confident *Hindi palagay* ☐Moderately confident *Katamtamangpalagay* ☐Very confident *Napakapalagay*

13. Educationalattainment. *NataposnaEdukasyon*

☐Elementary ☐High school ☐College ☐Post graduate ☐Vocational ☐Other/*Iba pa*

14. Monthlyfamilyincome .*Buwanangkita/sahodngpamilya*

☐Lessthan/*mababasa*P5,000 ☐P5,001-P10,000 ☐P10,001-P15,000 ☐P15,001-P20,000 ☐P20,001-P25,000 ☐ Morethan/*higitsa*P25,000

HHIE-S AGE 65 OR OVER

4) Please tick either No, Sometimes or Yes for each question.
Kudlitan (√) alimansa "Hindi", "Minsan" o "Oo" angbawattanong.

5) Do not skip a question if you avoid a situation because of a hearing problem.
Kung angsitwasyon ay iyonginiiwasandahilsaiyongpandinig, sagutin pa rinangtanong.

6) If you use a hearing aid, please answer according to the way you hear with the aid.
Kung ikaw ay gumagamitng "hearing aid", sagutinangbawattanongnanaaayonsaiyongpandinigkapaggamitang "hearing aid."

	No *Hindi*	Sometimes *Paminsan-minsan*	Yes *Oo*
1. Does a hearing problem cause you to feel embarrassed when you meet new people? *Nagdudulotbangkahihiyanangiyongpandinigkapagnakipagkilalakasabagongtao?*	☐ 0	☐ 2	☐ 4
2. Does a hearing problem cause you to feel frustrated when talking to members of your family? *Nagdudulotbangkabiguanangiyongpandinigkapagikaw ay nakikipag-usapsaiyongpamilya at kamag-anak?*	☐ 0	☐ 2	☐ 4
3. Do you have difficulty when someone speaks in a whisper?*Nahihirapankabangmakarinigkapagangtao ay nagsasalitangpabulong?*	☐ 0	☐ 2	☐ 4
4. Do you feel handicapped by a hearing problem? *May kapansanankabadahilsaiyongpandinig?*	☐ 0	☐ 2	☐ 4
5. Does a hearing problem cause you difficulty when visiting friends, relatives or neighbours? *Dahilsaiyongpandinig, nahihirapankabangmakipag-usapkapagbinibisitamoangmgakaibigan, kamag-anak o kapitbahay?*	☐ 0	☐ 2	☐ 4
6Does a hearing problem cause you to attend lectures or religious services less often than you would like?*Nang dahilsaiyongpandinig, bihirakana bang makihalubilo o magsimba?*	☐ 0	☐ 2	☐ 4
7. Does a hearing problem cause you to have arguments with family members? *Dahilsaiyongpandinig, nagkakaroonkabang di pagkakaunawaansaiyongpamilya?*	☐ 0	☐ 2	☐ 4
8. Does a hearing problem cause you difficulty when listening to TV or radio? *Dahilsaiyongpandinig, nahihirapangkabangmakarinigsatelebisyon o radio?*	☐ 0	☐ 2	☐ 4
9. Do you feel that any difficulty with your hearing limits or hampers your personal or social life? *Dahilsaiyongpandinig maylimitasyonbaangiyongpansarili or panlipunangbuhay?*	☐ 0	☐ 2	☐ 4
10. Does a hearing problem cause you difficulty when in a restaurant with relatives or friends?.*Dahilsaiyongpandinigmahirap bang makarinigkapagikaw ay nasakarinderyakasamaangmgakamag-anak o kaibigan?*	☐ 0	☐ 2	☐ 4
Totals:			

11. Do you feel that you need a hearing aid? *Sa palagaymo, kailanganmobaang "hearing aid"?*

☐No/*Hindi* ☐Maybe/*Marahil* ☐Yes/*Oo*

12. How confident are you in your ability to manage/use a hearing aid? *Gaanokapalagayangiyongloobsaiyongkakayahanggamitinang "hearing aid"?*

☐Not at all confident ☐Moderately confident ☐Very confident
Hindi palagay *Katamtamangpalagay* *Napakapalagay*

13. Educationalattainment. *NataposnaEdukasyon*

☐Elementary ☐High school ☐College ☐Post graduate ☐Vocational ☐Other/*Iba pa*

14. Monthlyfamilyincome .*Buwanangkita/sahodngpamilya*

☐Lessthan/*mababasa*P5,000 ☐P5,001-P10,000 ☐P10,001-P15,000 ☐P15,001-P20,000 ☐P20,001-P25,000 ☐Morethan/*higitsa*P25,000

Appendix C - Tagalog translation of the IOI-HA

To be filled up by the respondent
(*Susulatan ng respondente*)

International Outcome Inventory for Hearing Aids (IOI-HA)

1. Think about how much you used your present hearing aid(s) over the past two weeks. On an average day, how many hours did you use the hearing aid(s)? *Makaraan ang dalawang linggong paggamit ninyo ng hearing aid(s), ilang oras ninyo ito ginagamit sa loob ng isang araw?*

☐	☐	☐	☐	☐
None (*Wala*)	Less than 1 hour a day (*Kulang sa isang oras*)	1 to 4 hours a day (*1-4 oras*)	4 to 8 hours a day (*4-8 oras*)	More than 8 hours a day (*Mahigit 8 oras*)

2. Think about the situation where you most wanted to hear better before you got your present hearing aid(s). Over the past two weeks, how much has the hearing aid(s) help in that situation? *Alalahanin ninyo ang mga pagkakataon na gusting gusto ninyong makarinig nang mabuti na wala pa kayong hearing aid. Ngayong may hearing aid na kayo, gaano ang naitulong nito sa makalipas ang dalawang linggong paggamit nito?*

☐	☐	☐	☐	☐
Helped not at all (*Walang naitulong*)	Helped slightly (*Bahagyang nakatulong*)	Helped moderately (*May naitulong*)	Helped quite a lot (*Nakatulong nang katamtaman*)	Helped very much (*Nakatulong nang malaki*)

3. Think again about the situation where you most wanted to hear better. When you use your present hearing aid(s), how much difficulty do you still have in that situation? *Muling alalahanin ninyo ang mga pagkakataon na gustong gusto ninyong makarinig nang mabuti. Ngayon, may problema pa rin ba kayong nararanasan sa kasalukuyang paggamit ninyo ng hearing aid?*

☐	☐	☐	☐	☐
Very much difficulty (*Matinding matinding problema*)	Quite a lot of difficulty (*Matinding problema*)	Moderate difficulty (*May problema*)	Slight difficulty (*May bahagyang problema*)	No difficulty (*Walang problema*)

4. Considering everything, do you think your present hearing aid(s) is worth the trouble? *Sa kabuuan, sa palagay ba ninyo ay sulit ang paggamit ninyo ng hearing aid?*

☐	☐	☐	☐	☐
Not at all worth it (*Hindi sulit*)	Slightly worth it (*Sulit nang bahgya*)	Moderately worth it (*Sulit lang*)	Quite a lot worth it (*Higit ang pagkasulit*)	Very much worth it (*Sulit na sulit*)

5. Over the past two weeks with your hearing aid(s), how much have your hearing difficulties affected the things that you can do? *Sa nagdaang dalawang linggo na gamit ninyo ang hearing aid, gaano ito nakaapekto sa pang-araw araw na gawain?*

☐	☐	☐	☐	☐
Affected very much (*Matinding epekto*)	Affected quite a lot (*May malaking epekto*)	Affected moderately (*May epekto*)	Affected slightly (*May bahagyang epekto*)	Affected not at all (*Walang epekto*)

6. Over the past two weeks with your present hearing aid(s), how much do you think other people were bothered by your hearing difficulties? *Sa loob ng dalawang linggong paggamit ninyo ng hearing aid, sa inyong palagay, nakaapekto ba ito sa ibang tao?*

☐	☐	☐	☐	☐
Bothered very much (*May matinding epekto*)	Bothered quite a lot (*Madalas na epekto*)	Bothered moderately (*May epekto talaga*)	Bothered slightly (*Bahagyang nakaapekto*)	Bothered not at all (*Di nakaapekto*)

7. Considering everything, how much has your present hearing aid(s) changed your enjoyment of life? *Sa kabuuan, gaano ang naitulong ng hearing aid sa ikaliligaya ng inyong buhay?*

☐	☐	☐	☐	☐
Worse (*Lalong humirap*)	No change (*Walang naitulong*)	Slightly better (*May kaunting naitulong*)	Quite a lot better (*Malaki ang naitulong*)	Very much better (*Sobrang laking naitulong*)

Appendix D – Ethics approvals

John Newall

From:	Ethics Secretariat
Sent:	Monday, 27 August 2012 10:57 AM
To:	Mr John Newall
Cc:	E/Prof Philip Newall; Mr Rohan Biddulph
Subject:	Approved- Ethics application- Newall (Ref No: 5201200581)

Dear Mr Newall

Re: "Assessing the outcomes of a hearing aid donation program in the Philippines" (Ethics Ref: 5201200581)

The above application was reviewed by the Human Research Ethics Committee at its meeting on 24-Aug-12 . Final Approval of the above application is granted, effective 27 August 2013, and you may now commence your research.

This research meets the requirements of the National Statement on Ethical Conduct in Human Research (2007). The National Statement is available at the following web site:

http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72.pdf.

The following personnel are authorised to conduct this research:

E/Prof Philip Newall
Mr John Newall
Mr Rohan Biddulph

NB. STUDENTS: IT IS YOUR RESPONSIBILITY TO KEEP A COPY OF THIS APPROVAL EMAIL TO SUBMIT WITH YOUR THESIS.

Please note the following standard requirements of approval:

1. The approval of this project is conditional upon your continuing compliance with the National Statement on Ethical Conduct in Human Research (2007).

2. Approval will be for a period of five (5) years subject to the provision of annual reports.

Progress Report 1 Due: 27 August 2013
Progress Report 2 Due: 27 August 2014
Progress Report 3 Due: 27 August 2015
Progress Report 4 Due: 27 August 2016
Final Report Due: 27 August 2017

NB. If you complete the work earlier than you had planned you must submit a Final Report as soon as the work is completed. If the project has been discontinued or not commenced for any reason, you are also required to submit a Final Report for the project.

Progress reports and Final Reports are available at the following website:

http://www.research.mq.edu.au/for/researchers/how_to_obtain_ethics_approval/
human_research_ethics/forms

3. If the project has run for more than five (5) years you cannot renew

approval for the project. You will need to complete and submit a Final Report and submit a new application for the project. (The five year limit on renewal of approvals allows the Committee to fully re-review research in an environment where legislation, guidelines and requirements are continually changing, for example, new child protection and privacy laws).

4. All amendments to the project must be reviewed and approved by the Committee before implementation. Please complete and submit a Request for Amendment Form available at the following website:

http://www.research.mq.edu.au/for/researchers/how_to_obtain_ethics_approval/human_research_ethics/forms

5. Please notify the Committee immediately in the event of any adverse effects on participants or of any unforeseen events that affect the continued ethical acceptability of the project.

6. At all times you are responsible for the ethical conduct of your research in accordance with the guidelines established by the University. This information is available at the following websites:

http://www.mq.edu.au/policy/

http://www.research.mq.edu.au/for/researchers/how_to_obtain_ethics_approval/human_research_ethics/policy

If you will be applying for or have applied for internal or external funding for the above project it is your responsibility to provide the Macquarie University's Research Grants Management Assistant with a copy of this email as soon as possible. Internal and External funding agencies will not be informed that you have final approval for your project and funds will not be released until the Research Grants Management Assistant has received a copy of this email.

Please retain a copy of this email as this is your official notification of final ethics approval.

Yours sincerely
Dr Karolyn White
Director of Research Ethics
Chair, Human Research Ethics Committee

From: Ethics Secretariat

Sent: Tuesday, 30 August 2011 3:41 PM

To: Mr John Newall

Cc: teagan.young@students.mq.edu.au

Subject: Final Approval- Ethics application reference-5201100475 (M)

Dear Mr Newall

Re: "Socioeconomic status, access to healthcare and hearing loss in rural and urban Filipino populations"

(Ethics Ref: 5201100475)

Thank you for your recent correspondence. Your response has addressed the issues raised by the

Human Research Ethics Committee and you may now commence your research.

The following personnel are authorised to conduct this research:

Mr John Newall- Chief Investigator/Supervisor Mrs Teagan Young & Professor Philip Newall- Co-

Investigators

NB. STUDENTS: IT IS YOUR RESPONSIBILITY TO KEEP A COPY OF THIS APPROVAL EMAIL TO SUBMIT

WITH YOUR THESIS.

Please note the following standard requirements of approval:

1. The approval of this project is conditional upon your continuing

compliance with the National Statement on Ethical Conduct in Human Research (2007).

2. Approval will be for a period of five (5) years subject to the provision

of annual reports. Your first progress report is due on 30 August 2012.

If you complete the work earlier than you had planned you must submit a Final Report as soon as the

work is completed. If the project has been discontinued or not commenced for any reason, you are also

required to submit a Final Report for the project.

Progress reports and Final Reports are available at the following website:

http://www.research.mq.edu.au/for/researchers/how_to_obtain_ethics_approval/

human_research_ethics/forms

3. If the project has run for more than five (5) years you cannot renew

approval for the project. You will need to complete and submit a Final Report and submit a new

application for the project. (The five year limit on renewal of approvals allows the Committee to fully re-

review research in an environment where legislation, guidelines and requirements are continually

changing, for example, new child protection and privacy laws).

4. All amendments to the project must be reviewed and approved by the

Committee before implementation. Please complete and submit a Request for Amendment Form

available at the following website:

http://www.research.mq.edu.au/for/researchers/how_to_obtain_ethics_approval/

human_research_ethics/forms

5. Please notify the Committee immediately in the event of any adverse

effects on participants or of any unforeseen events that affect the continued ethical acceptability of the

project.

6. At all times you are responsible for the ethical conduct of your

research in accordance with the guidelines established by the University.

This information is available at the following websites:

http://www.mq.edu.au/policy/

http://www.research.mq.edu.au/for/researchers/how_to_obtain_ethics_approval/

human_research_ethics/policy

If you will be applying for or have applied for internal or external funding for the above project it is your

responsibility to provide the Macquarie University's Research Grants Management Assistant with a copy

of this email as soon as possible. Internal and External funding agencies will not be informed that you

have final approval for your project and funds will not be released until the Research Grants

Management Assistant has received a copy of this email.

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