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ARCHS: adult recipients of cochlear implants: health and social long-term outcomes–a state-specific and national population-based retrospective cohort study protocol

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ABSTRACT

Introduction While the majority of adults with severe-to-profound hearing loss and poor speech perception outcomes with hearing aids benefit from receiving a cochlear implant, the long-term health and social benefits for implant recipients are yet to be explored. The objective of the ARCHS research is to provide a better understanding of the health and social factors that play a role in the lives of adults with a cochlear implant up to 10 years after the procedure.

Method and analysis This research will involve conducting two retrospective cohort studies of adults aged ≥18 years who received a cochlear implant during 2011–2021 using linked administrative data first within New South Wales (NSW) and second Australia-wide. It will examine health service use and compare health and social outcomes for younger (18–64 years) and older (≥65 years) cochlear implant recipients.

Ethics and dissemination Ethical approval was received from the NSW Population Health Services Research Ethics Committee for the NSW cohort study (Reference: 2022/ETH00382/2022.07) and from the Macquarie University ethics committee for the national cohort study (Reference: 520221151437084). Research findings will be published in peer-reviewed journals and presented at scientific conferences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The population-based cohort studies will establish a comprehensive profile of adult cochlear implant recipients in Australia.
⇒ The studies will involve a detailed exploration of adult cochlear implant recipients and the association of the implant with their health and social outcomes.
⇒ Record linkage of population-based administrative data collections at both statewide and national levels.
⇒ Potential for underenumeration of comorbidities, as only comorbidities that are relevant to a hospital admission or based on dispensed subsidised medications would be identified.

INTRODUCTION

Internationally, an estimated 450 million people have disabling hearing loss.[1] Within Australia, around one in seven adults have indicated that they have some form of hearing loss, with 112 500 adults indicated to have severe hearing loss.[2] Hearing loss can occur gradually and often becomes worse over time with increasing age.[3] Adults with more severe hearing losses may be candidates to receive a cochlear implant, in particular when they receive limited benefits from hearing aids. Cochlear implants provide a sense of hearing by electrically stimulating the auditory neurons via electrodes placed in the cochlea.

Through the microphone of an external device (the sound processor), sounds are picked up, transformed in a patterned electric signal, and delivered to the implanted electrodes. These signals can then be interpreted as sounds by the brain.[4] However, there are limitations to the quality of hearing that can be achieved with a cochlear implant, with variability in outcomes experienced by cochlear implant recipients.[5]

Previous reviews of outcomes of cochlear implantation in adults have identified that the majority of adults who receive a cochlear implant improve their speech perception with this intervention[3 5] and that unilateral cochlear implants can improve their health-related quality of life[3 6] and social experiences.[7] However, most studies examining the health and social impact of cochlear implantation have not been population based,[8] have involved short-term follow-up studies (eg, 3 months) with a relatively low number of participants (ranging from 30 to

864 participants)[3] or only focused on one subpopulation group, such as older adults aged ≥65 years.[9]

There have been recommendations for research to examine the impact of cochlear implants among adults that would be of longer duration and that would involve large databases or registries, where longer-term follow-up of health and social outcomes would be possible.[3] Little is known about the ongoing primary and specialist health service use, general health, social outcomes, educational pathways, training opportunities and career trajectories of adults who have received a cochlear implant and whether outcomes differ for different subcohorts of cochlear implant recipients.

Study objectives and aims

The ARCHS (Adult Receipents of Cochlear implants: Health and Social long-term outcomes) research study will involve conducting two multipurpose, population-based retrospective cohort studies. The first cohort study will examine health service use and treatment cost of adults who have received at least one cochlear implant in New South Wales (NSW), Australia and the second cohort study will examine the long-term health and social outcomes of adults who received a cochlear implant Australia-wide between 2011 and 2021. The two cohort studies will access different types of records (see the Data sources section). The NSW cohort will access hospitalisation and mortality records, while the national cohort will access primary and specialist care, education and training, and general health and social records. Each cohort study will provide a different snapshot on the health and other factors that have influenced the lives of adults who received a cochlear implant.

The overall objective of the NSW cohort study is to examine the characteristics and health service use of adults who received a cochlear implant in NSW. The specific aims are to:

1. Identify the number, characteristics and treatment cost of hospital admissions for adults who have received a cochlear implant.
2. Examine the health service use of younger (18–64 years) and older adults (≥65 years) who have received a cochlear implant.
3. Compare health outcomes for younger and older adults who received a cochlear implant.

The overall objective of the national cohort study is to examine the primary and specialist health service use, general health, social outcomes, educational pathways, training opportunities and career trajectories of adults who received a cochlear implant in Australia. The specific aims are to:

1. Identify the type and characteristics of primary and specialist health services in use for adults who have received a cochlear implant.
2. Examine the general health and social outcomes of younger and older adults who received a cochlear implant.

3. Explore educational, training and career pathways for adults who have received a cochlear implant by key demographic characteristics.

Method and analysis

Study design

Two population-based retrospective cohort studies, one cohort in NSW and one cohort Australia-wide.

Data sources

The NSW cohort study will use information on health service use, treatment cost and survival obtained from non-admitted and admitted patient, cost and mortality data collections. The non-admitted patient data includes information on all non-admitted patient clinical or therapeutic services and includes client demographics, service date, provider type and types of service contacts. Hospital admission data includes information on admissions to public and private hospitals and records of patient demographics, diagnoses, clinical procedures and Australian Refined Diagnosis Related Groups. Mortality data from the NSW Registry of Births, Deaths and Marriages deaths data will provide information on the fact of death and information from the Cause of Death Unit Record File will provide information on the cause of death.

The national cohort study will use administrative data on general health, primary and specialist healthcare service use, social outcomes, education and training, and career pathways accessed from the multiagency data integration project (MADIP), a longitudinal data asset developed by the Australian Bureau of Statistics (ABS).[10] The MADIP modules that will be accessed include the:

► Core module (ie, demographic information derived from the census (eg, age, sex), death registration and personal income tax).
► Geography module (eg, urban/rural/remote residence, socioeconomic status).
► Medicare Benefits Schedule (ie, primary and specialist healthcare visits).
► Pharmaceutical Benefits Scheme (ie, prescribed medication);
► Department of Social Services data over multiple individual occurrences Centrelink Administrative data (ie, government assistance).
► Personal income tax (ie, total income).
► Apprentice and trainee database.
► Higher education database.
► Australian census and ABS surveys, including the Census of Population and Housing (ie, demographics, living arrangements, working life),[11] the National Health Survey (ie, general health status)[12] and the Survey of Disability, Ageing and Carers (ie, health and service support).[13]

Case inclusion criteria

Both the NSW and national studies will include adults aged ≥18years who received a cochlear implant during 1 January 2011 to 31 December 2021. Within the NSW

study, the cochlear implant procedure (ie, procedure: 4161700) in either the principal or any subsequent procedure codes will be used to identify adults who had a cochlear implant inserted in an NSW hospital. Within the national study, an MBS item number indicating the person received a cochlear implant (ie, item: 41617) will be used to identify cohort members.

Within Australia, cochlear implantation services can be either publicly or privately funded through private health insurers.[14] Due to the mixed nature of funding arrangements, candidacy for cochlear implantation is generally considered for each ear, rather than the better hearing ear.[14] The candidacy criteria is generally based on the probability of a person to obtain better hearing results with a cochlear implant compared with existing hearing abilities, including with hearing aids. Specifically, adults with postlingual hearing loss can be considered for a cochlear implant if they obtain scores of up to 55% for open-set phonemes in quiet in their affected ear.[15] However, both candidacy criteria and the availability of funding can vary between Australian jurisdictions and between clinics within the same jurisdiction.[14]

Sample size calculation

There will be an estimated 3500 adults in NSW and 8754 adults Australia-wide who received a cochlear implant during 2011–2021. These estimates represent the total population. To detect a relative risk of 1.5 with a 5% significance and 80% power, a minimum sample size of 220 cases will be required.

Record linkage

The record linkage of administrative data for the NSW and national cohorts will be conducted by third party agencies to protect the identity of cohort members. The NSW linkage will be conducted by the Centre for Health Record Linkage (CHeReL) and the national linkage will be conducted by the ABS. Both agencies will use probabilistic linkage methods to link records within and between data collections, based on the probability that records belong to the same person. A project specific linkage key for each person will be created during the linkage process.

Within NSW, the data custodian (or the CHeReL Data Integration Unit) will provide extracts of the approved content data for analysis to the researchers via a secure data transfer mechanism. The researchers will then organise and link the data extracts using each person's project specific linkage key. For the national study, extracts of content data for analysis will be generated by the ABS. Data organisation and analysis will be undertaken by the researchers within the ABS's secure DataLab facility.

Classification frameworks
Geographic location

The Australian Statistical Geographical Standard (ASGS) will be used to identify rural and urban residents by using the statistical area level 2 (SA2) as an indicator of residential location. The ASGS assigns residents to one of five categories (ie, major cities, inner regional, outer regional, remote and very remote) using defined index scores of distance to service centres.[16] For ease of analysis and reporting, the five categories will be collapsed into two categories: urban (ie, major cities) and rural (ie, inner and outer regional, remote and very remote).

Socioeconomic status

A measure of socioeconomic status will be assigned to each person using the index of relative socioeconomic disadvantage, using SA2 as an indicator of residential location. The index is derived from Australia's population census using information such as income, education, employment and occupation.[17] Socioeconomic disadvantage will be partitioned into quintiles from most (ie, 1) to least disadvantaged (ie, 5).

Comorbidities and health status

Within the NSW cohort, the 17 Charlson Comorbidity Index will be identified by using up to 50 diagnosis classifications in the hospitalisation records and using a 12-month look-back period.[18] Within the national cohort, the Rx-Risk comorbidity index will be used to identify 46 comorbidities using the Pharmaceutical Benefits Scheme data.[19] In addition, the National Health Survey will be used to provide information on general health status.[12]

Outcomes

Within the NSW cohort, the primary outcome is the number of hospital admissions during the study time frame. The secondary outcomes are the direct hospital treatment cost associated with the hospital admissions; number of non-admitted occasions of service and health outcomes, such as hospital length of stay, hospital readmission within 28 days and 30-day mortality.

Australia-wide, the primary outcomes are a number of primary and specialist care visits during the study time frame. The secondary outcomes will include tertiary education, use of apprentice and training schemes, income, use of government financial assistance (table 1).

Data analysis plan

Analyses will be performed using SASV.9.4 (SAS Institute). For the NSW cohort, descriptive statistics (eg, frequency, per cent, sum, mean, median, SD) will be used to describe the cohort characteristics and to report the treatment costs. χ^2 tests of independence will be used to compare key characteristics (such as age group, sex, number of comorbidities, urban or rural residential location, socioeconomic status) and linear regression will be used to compare factors associated with younger and older adults and their health service use (ie, hospital admissions, non-admitted occasions of service). Regression models (ie, linear, logistic, binomial/Poisson depending on the outcome assessed and its prevalence) will be used to compare factors associated with younger and older adults and their health outcomes (eg, hospital

Table 1 Health and social outcome measures

Outcome	Data source	Outcome measure
NSW Cohort		
Health service use and survival		
Non-admitted client contacts	Non-admitted patient data	No of non-admitted client contacts
Hospital admissions	Hospital admissions data	No of hospitalisations
Hospital length of stay	Hospital admissions data	Total hospital length of stay
Hospital treatment cost	Hospital admissions data	Total hospital treatment cost
Hospital readmissions	Hospital admissions data	Readmission within 28 days
Survival	RBDM – deaths data	30-day mortality
National cohort		
Health service use and survival		
Primary care	Medicare Benefits Schedule	No of general practitioner visits
Specialist care	Medicare Benefits Schedule	No of specialist visits
Survival	National Death Index	Mortality
Education and training		
Higher education	Higher education database	Completed tertiary education
Apprentice and traineeship	Apprentice and Trainee database	Completed apprentice or traineeship
Income and financial assistance		
Income	Personal income tax	Total income
Government financial assistance	DOMINO Centrelink Administrative Data	Received government financial assistance

DOMINO, Data Over Multiple Individual Occurrences; NSW, New South Wales; RBDM, Registry of Births, Deaths and Marriages.;

length of stay, readmission to hospital within 28 days). Relative risks, Odds ratios (OR) and 95% CIs will be calculated.

For the national cohort, descriptive statistics (eg, frequency, percent, mean, median, SD) will be used to describe the cohort characteristics and to report the health service use based on key demographic characteristics. χ^2 tests of independence will be used to compare key characteristics and multivariable regression will be used to compare factors associated with younger and older adults and their health (eg, number of general practitioner/specialist visits) and social outcomes (eg, government assistance). Regression models (ie, linear, logistic, multinominal depending on the outcome assessed and its prevalence) will be used to compare key characteristics of adults with a cochlear implant and their social outcomes (eg, tertiary education, training, income bracket). Relative risks, ORs and 95%CIs will be calculated.

For both the NSW and national cohorts, covariates will be controlled in statistical analyses and will include: age group, sex, comorbidities, alcohol use and dependence, drug use and dependence, mental health conditions, Indigenous status (Y/N), urban/rural residential location, socioeconomic status and language spoken at home.

Ethics and dissemination
Ethical approval and a wavier of consent for the NSW cohort study was obtained from the NSW Population Health Services Research Ethics Committee (Reference: 2022/ETH00382/2022.07) and ethical approval and a waiver of consent for the national cohort study was obtained from the Macquarie University HREC Medical Sciences Committee (Reference: 520221151437084). Dissemination of research results will be conducted through a number of mechanisms, including peer-review journal articles and presented at professional conferences. Research findings will also be provided to government agencies.

Patient and public involvement
Two adult consumers who have received cochlear implants will be recruited and paid to provide lived experience to the ARCHS research. The two consumers will inform the prioritisation of research questions and data interpretation within ARCHS. The consumers will be instrumental in providing lived experience of using a cochlear implant and their views on access to services and support.

LIMITATIONS
There will likely be some limitations associated with the research. Within both the NSW and national cohorts,

identification of comorbidities could be underenumerated, as only comorbidities that are relevant to a hospital admission are indicated in hospital diagnosis records and only comorbid conditions based on dispensed subsidised medications would be identified, respectively. There will not be an opportunity to examining the validity of administrative data records, and it is possible that there could be some misclassification. There are known limitations with estimating relative risks, in that a relative risk does not provide information on the absolute risk of an event occurring. However, estimating a relative risk does provide information on the risk of an event occurring within groups.[20]

DISCUSSION

The ARCHS research will use a novel big data approach to provide a better understanding of the social (eg, socioeconomic status, demographics), education and health (eg, comorbidities) factors that play either a positive or negative role in the lives of adults with a cochlear implant and explore factors that create or hinder resilience among adults with a cochlear implant. Research results will highlight the primary, non-admitted, acute and specialist health services use by adults who have cochlear implants over time. The research will examine the life trajectories of adults with a cochlear implant up to 10 years after their implant, consider the nexus of health, social and environmental factors and their influence on outcomes, and compare outcomes of younger and older cochlear implant recipients adults. Identification of receipt of tertiary education and use of apprentice and training schemes, along with career pathways for adults who have received a cochlear implant, will be explored. The ARCHS research will also consider preimplant predictive factors that could identify cochlear implant candidates with highly positive or those at-risk of poor outcomes. ARCHS aims to identify opportunities to improve health and social outcomes for adults with a cochlear implant and identify potential gaps in service delivery.

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