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Developing a new quality of life instrument with older people for economic evaluation in aged care: study protocol

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ABSTRACT

Introduction The ageing of the population represents a significant challenge for aged care in Australia and in many other countries internationally. In an environment of increasing resource constraints, new methods, techniques and evaluative frameworks are needed to support resource allocation decisions that maximise the quality of life and well-being of older people. Economic evaluation offers a rigorous, systematical and transparent framework for measuring quality and efficiency, but there is currently no composite mechanism for incorporating older people's values into the measurement and valuation of quality of life for quality assessment and economic evaluation. In addition, to date relatively few economic evaluations have been conducted in aged care despite the large potential benefits associated with their application in this sector. This study will generate a new preference based older person-specific quality of life instrument designed for application in economic evaluation and co-created from its inception with older people.

Methods and analysis A candidate descriptive system for the new instrument will be developed by synthesising the findings from a series of in-depth qualitative interviews with 40 older people currently in receipt of aged care services about the salient factors which make up their quality of life. The candidate descriptive system will be tested for construct validity, practicality and reliability with a new independent sample of older people (n=100). Quality of life state valuation tasks using best worst scaling (a form of discrete choice experiment) will then be undertaken with a representative sample of older people currently receiving aged care services across five Australian states (n=500). A multinomial (conditional) logistical framework will be used to analyse responses and generate a scoring algorithm for the new preference-based instrument.

Ethics and dissemination The new quality of life instrument will have wide potential applicability in assessing the cost effectiveness of new service innovations and for quality assessment across the spectrum of ageing and aged care. Results will be disseminated in ageing, quality of life research and health economics journals and through professional conferences and policy forums. This study has been reviewed by the Human Research Ethics Committee of the University of South Australia and has ethics approval (Application ID: 201644).

Strengths and limitations of this study

► The new quality of life instrument developed will be co-created with older people and will provide a composite mechanism or incorporating older people's values into the measurement and valuation of quality of life for quality assessment and economic evaluation.
► Inclusivity will be enhanced by incorporating the preferences of older people from a variety of care settings (including those with mild cognitive impairment and mild dementia, previously excluded from research of this nature) in the development, validation and valuation of the new instrument.
► The study has a broad range of investigators with input into the study protocol from consumers, aged care practitioners and providers.
► The best worst scaling approach utilised for the valuation may not be easily understood by older people receiving aged care services and therefore this may limit their ability to value quality of life from their own perspective.
► The ability of the study to generate a new quality of life instrument which is co-developed with and representative of older people receiving aged care services may be compromised if older people from a variety of care settings do not elect to participate.

INTRODUCTION

People, aged 65 years and over, represent a rapidly growing age group and are major users of health and aged care services. In 2013 to 2014, recurrent Australian Government expenditure on aged care programmes and services was $14.8 billion and this is forecast to increase to $80 billion by 2054 to 2055.[1] Annual health system expenditures for older people are four to five times higher than those in their early teens and increase exponentially beyond 65 years of age.[1] Recently, a number of policy initiatives have been introduced to break down boundaries in care settings and build partnerships between aged

care organisations and the healthcare sector.[2 3] Examples include the use of multi-disciplinary aged care teams and mechanisms to allow services traditionally provided in a hospital setting to be provided in the community, in an older person's home or within aged care facilities. These reforms have been designed to reduce fragmentation and to improve quality and efficiency in the care provided to older people.[2 3] Economic evaluation is a powerful tool that can help decision makers across health and aged care sectors to drive quality and efficiency improvements and thereby make the most of limited resources. Economic evaluation offers a systematical and robust methodological framework for comparing the costs and outcomes of new and existing services and programmes.[4 5]

The measurement and valuation of quality of life represents the cornerstone of cost utility analysis, the most prevalent form of economic evaluation. Within cost utility analysis, outcomes are typically captured and reported in terms of quality adjusted life years (QALYs). The QALY combines quality of life and length of life into a single index on a '0' to '1' (dead - full health) scale. As a generic measure, the QALY facilitates comparisons of the benefits generated from disparate interventions.[5] Despite the label 'quality of life', to date QALY's have narrowly focused on health status. This priority may be viewed as appropriate for curative interventions in the healthcare sector where the main objective is to improve health.[5] However, the aged care sector has broader and more inclusive goals, especially those that emphasise improvements to the quality of life and well-being of older people.[5 6] Prior research conducted by our team strongly indicates that quality of life attributes that transcend health, for example, independence and control, social participation, safety and dignity are highly valued by older people.[7 8] Many innovations in aged care seek to improve the quality of life of older people by promoting these quality of life attributes. For example, consumer directed care empowers older people to live independently through the ability to exercise autonomy and choice.[9] Similarly emerging models of reablement seek to maintain an older person's capacity to live as independently as possible and actively participate in home-life, community and society.[10] While such models of care may not impact directly on the health status of an older person, they may result in cost savings to government and society while delivering overall improvements in quality of life.

Our team has successfully conducted two pilot studies highlighting the central importance of quality of life attributes to older people. Our first pilot study employed a mixed methods (quantitative and qualitative) design with two separately convened focus groups of older people (n=21) recovering from illness.[7] While health status was valued as an important contributor to overall quality of life, other broader aspects of quality of life including independence, control and social relationships were also consistently highly valued.[7] Our large-scale pilot study, recently published in the international journal *Quality of*

Life Research compared the preferences of younger adults aged 18 to 64 years (n=500) with those of older adults aged 65 years and above (n=500) as to the relative importance of key quality of life attributes using ranking and best worst scaling (BWS - a form of discrete choice experiment or DCE).[8] The findings from this study indicated that the preferences of younger and older people in relation to the relative importance of the attributes of quality of life embedded in health status and broader attributes of quality of life were not the same. The ability to be independent, physically mobile and have control over their daily lives were found to be the most important determinants of older people's quality of life. It is important to note that while existing preference based instruments, including the EuroQoL (EQ)-5D and the adult social care outcomes toolkit (ASCOT) incorporate some of these elements, no currently existing preference based instrument incorporates all three of these quality of life attributes for the calculation of QALYs. Many recent innovations in service delivery targeted for older people including consumer directed care, reablement and frailty interventions are designed to improve older peoples' ability to be independent, physically mobile and have control over their daily lives.[9 10] The new instrument will provide a robust mechanism for capturing these attributes within quality adjusted life years for economic evaluation. New methods, techniques and evaluative frameworks are needed to overcome resource constraints while maximising the quality of life and well-being of older people.

This project will fill this gap through the development of a new preference based older person-specific quality of life instrument designed for application in economic evaluation and co-created from its inception with older people.

AIMS
This study has three main objectives:
► Identify the quality of life attributes relevant to older people in receipt of aged care, going beyond those captured by existing instruments.
► Develop and validate the descriptive system for the new quality of life instrument to appropriately capture those attributes.
► Engage older people with discrete choice experiments to produce a scoring system for the new instrument that is compatible with the QALY scale and has wide applicability for economic evaluation.

METHODS AND ANALYSIS
This three-phase multimethod project will be conducted over a 3 year time frame (January 2019 to December 2021) and will use a qualitative and quantitative design including semi-structured interviews and DCE's. We will build on the methodological and project management approaches successfully employed by our team in our previous Australian Research Council linkage project to develop a health economics model for the development

and evaluation of consumer directed care in community aged care services.[9] A particular strength of our proposed project is its inclusivity. We will build on our collective research and practical stakeholder experience to incorporate the preferences of older people from a variety of care settings (including those with mild cognitive impairment and mild dementia, previously excluded from research of this nature) in the development, validation and valuation of the new quality of life instrument. The research team has extensive experience in recruitment and the conduct of research studies with older people including those with cognitive impairment, the development of aged care services for older people and the translation of research into practice.

Patient and public involvement

The research question and the need for a new older person-specific quality of life instrument designed for economic evaluation and developed from its inception with older people in receipt of aged care was directly informed by our prior research working in partnership with older people in community settings.[7–9] Our chief investigator team and project advisory group includes consumer representatives who have actively contributed to the study design. Older people (aged 65 years and above) will be integrally involved in all stages of the project via the client base of our partner organisations aged care services in South Australia (ECH and Helping Hand), Victoria (Uniting Age Well), Australian Capital Territory and New South Wales (Uniting ACT NSW and Presbyterian Aged Care). We will recruit participants with a range of cognitive abilities including older people living with mild cognitive impairment and mild dementia, (defined according to a mini-mental state examination (MMSE) score of 19 to 23) according to their prevalence among older people in receipt of aged care services.

Collectively, our team has extensive experience in incorporating the values and preferences of older people in all stages of study design and delivery, including those with mild cognitive impairment and mild dementia. We have demonstrated in several previously successful studies through the careful development and application of the methodological approaches adopted for this study (including discrete choice experiments) that older people with mild cognitive impairment and mild dementia are able to provide informed consent, fully participate and provide highly valuable insights in assessing their values and preferences in relation to quality of life and quality of care.[11–13] Individuals who are unable to communicate in English, with moderate or severe dementia and/or delirium will be excluded. Older people will be optimally supported to participate in all phases of the project by enabling participation from a variety of care settings including the older person's home, community centre, retirement village or aged care facility and at a time to suit their (and, if necessary, their family carers) needs.

Information about the project and its findings will be communicated to study participants, the aged care sector and the general community via our participating organisations' external relations units who target local, state and national web, print and electronic media. A website will also be developed for publishing outcomes and key findings from the project for participants, their families and the general public, as well as a final report on the conclusions of the project.

Phase 1: development of the descriptive system
Research design

The first phase of the project will address **Aim 1**. A descriptive system for the new instrument will be developed which encapsulates the key attributes of quality of life from the perspective of older people. Traditionally, descriptive systems for existing preference-based measures of quality of life have been developed using top down methods whereby the content of descriptive systems has been derived from existing measures and/or the literature. A contrasting approach is to employ a bottom up approach using qualitative research methods which encompasses the views of older people themselves about the factors which make up their quality of life. This approach will ensure the descriptive system has appropriate language, facilitate content validity and responsiveness to change. Qualitative research methods have been used successfully recently in the development of descriptive systems for several preference based instruments and are recommended as best practice methods for guiding attribute selection.[14 15]

Data collection

A series of qualitative semi-structured interviews will be conducted initially with older people who consent to be interviewed. Participants will be purposively chosen to reflect a range of socio-demographical characteristics including: age, gender, living situation (living alone or with family/carer or in the role of an older family carer), location (urban vs country areas), physical functioning (absence or presence of physical impairment), cognitive functioning (absence or presence of mild cognitive impairment and mild dementia) and the level of aged care services being received (home care package level). Our previous experience and recommendations from the literature indicate that a maximum sample size of n=40 will be sufficient to reach 'data saturation' (ie, where no new views or themes are expressed).[16] The qualitative interviews will be semi-structured and designed to build on our previous pilot studies to confirm the content and interpretation of the key quality of life attributes for older people. The interviews will probe factors and issues relating to quality of life including:

► What does the term 'quality of life' mean to an older person?
► How does quality of life relate to health status?
► What are the defining characteristics or attributes that determine the quality of life of older people?

The interviews will also investigate the relationship between quality of life and the characteristics of the older

person and/or their environment (eg, older people living with mild cognitive impairment and mild dementia, older people living in country vs urban areas).

Data analysis

All interviews will be recorded and transcribed verbatim and data entered into the qualitative data analysis software package NVivo to assist in the analysis. Thematic content analysis will be conducted involving three stages, according to established methods to provide a descriptive, or thematic, account.[17] The first stage will involve detailed listening, reading and re-reading of each interview transcript, to allow for continual data immersion. The second stage will involve the process of coding parts of the interview transcripts, sorting and tagging data to develop a coding framework and the final stage will involve identifying links between codes and the creation of broader categories or overriding themes in the data. A coding diary and coding map will be maintained to track the progression of the analysis until the research team has agreed the final themes for the descriptive system. The inductive analysis will be used together with the findings from our previous pilot studies and best practice guidance from the methodological literature to inform the development of the draft descriptive system.[14 18] The qualitative interviews will be used to guide the wording of the attributes and the categorisation and wording of the levels attached to each attribute to ensure that all language is clear, relevant and understandable to the intended population. Negatively worded questions will be avoided and the levels assigned to each attribute will be ordinal, with discrete responses for the instrument attributes.[14 18 19]

Phase 2: development and validation of the new descriptive system

Research design

The second phase of the project will address **Aim 2**. Psychometric testing will be employed to assess the construct validity, practicality and reliability of the newly developed descriptive system.

Data collection

Psychometric testing will be undertaken with a new independent sample of older people recruited via our partner organisations care networks previously specified. Our previous experience indicates that a sample size of n=100 will be sufficient to adequately represent and evaluate the psychometric properties.[5 16 17] Construct validity is defined as the extent to which the description comprehensively covers the different attributes of quality of life, is sufficiently sensitive to change and the quality of life state descriptions appears to be realistic. Participants will be asked to rank the levels of each attribute in order of their severity, to complete the instrument and provide feedback on the descriptions of the attributes and levels.

Data analysis

In addition to the participant feedback highlighted above, the level rankings will be analysed empirically using mean

rankings and variation and by using Kendall's coefficient of concordance test statistic.

Factor analysis will be undertaken to ensure the instrument uses the minimum number of items to represent the attributes of quality of life included.[14] The practicality of administering the new instrument depends on its acceptability to older people and the cost of administration (in terms of time).[18–20] This will be investigated by assessing how long the instrument takes to administer in different populations (eg, differentiated according to the presence or absence of mild cognitive impairment), different modes of administration (eg, electronic or hard copy version) and settings and the proportion of completed responses. Our recent related research has found that with an appropriate level of support, many people classified with mild or moderate cognitive impairment or dementia are able to provide a valid assessment of their own quality of life.[21] Our team will focus on the development of easy read resources and pictographs to assist in effectively communicating the content of the new descriptive system and facilitating understanding for older people with cognitive impairment and dementia.

Reliability is the ability of a descriptive system to produce the same responses on two separate occasions when there has been no change in quality of life.[18 19] This will be assessed by a sub sample of participants (n=40) who will complete the instrument on two separate occasions separated by an interval of 1 week. The results from each stage of the psychometric testing will be used to inform any refinement of the descriptive system prior to valuation.

Phase 3: determining weights for the descriptive system using DCE methodology

Research design

The third phase of the project will address **Aim 3,** determining the relative value or weight assigned to each attribute defined by the descriptive system and to produce a preference based scoring algorithm for the calculation of QALYs for economic evaluation.[5 22 23] Our previous DCE studies with older people have indicated that an interview mode of administration is preferable to self-completion postal or online surveys as this helps to aid participant understanding and promotes completion rates.[11–13] The BWS task will be developed for administration via a face-to-face interview and will be piloted prior to the main study with a small number of older people (n=10) to ensure that the task is easily understood and completion rates are maximised. The optimal sample size for the BWS task is dependent on the final number of attributes and levels included within the descriptive system and will be determined by consideration of the requirements of the BWS task and by the key objective of deriving older person-specific quality of life state values from a large and inclusive sample of older people from a variety of care settings.

Data collection

For a descriptive system comprising nine attributes with five levels assigned to each attribute a target sample size of n=500 older people will ensure precise estimation of model parameters for development of the scoring algorithm, while also protecting against any extremes of heterogeneity in preferences.[22–24] A fractional factorial design will be generated to reduce the number of quality of life states to a manageable number for the purposes of a face-to-face interview while retaining statistical efficiency for the estimation of model parameters. For example, a fractional factorial that permits the estimation of main effects for a DCE with nine attributes each with five levels, (while maintaining the design properties of efficiency and level balance) may be generated in 50 scenarios. We propose to block the design into five versions so that each participant is presented with a maximum of 10 scenarios for the BWS task. This will promote participant completion rates and minimise error due to fatigue. It has been demonstrated that large sample properties can be achieved with 50 respondents per block or version.[25] The presentation of five versions with 50 respondents per version therefore requires a total minimum sample size of 250 respondents. A sample size of 500 will therefore be sufficient to assess any differences in preference structure between participant sub-groups (eg, older people living with and without mild cognitive impairment, older people living in rural or more remote vs urban areas, older people recruited from community vs residential aged care settings).

The valuation survey will be comprised of three main sections. First, participants will be asked to indicate their level of agreement with a series of attitudinal statements relating to quality of life and it's description and definition on a 5-point Likert scale (ranging from completely agree to completely disagree). The attitudinal statements will be drawn from the findings of the initial qualitative interviews and will act as a warm up task to familiarise the participants with the topic and the descriptions to be included within the BWS task. Second, participants will be presented with a series of quality of life states presented one at a time and asked to indicate the best and worst attribute for each state. Each scenario will include a range of high, moderate and low levels for attributes rather than predominantly a consistently 'high' or 'low' selection of attribute levels. Each quality of life state description will consist of the common attributes of the new quality of life instrument with different levels for each of the states presented. Third, socio-demographical information including age, gender, health status as measured by the EQ-5D[26 27] and the level of aged care services being received will be collected at the final phase of the survey to facilitate sub-group analyses. The length of time spent completing the survey will be measured for each participant and they will also be asked to indicate how difficult they found the task to complete.

Data analysis

Paired and marginal models for the prediction of quality of life state values will be estimated using data from the BWS task. The BWS data will first be analysed using conditional logistical regression models. These will be used to estimate paired (maxdiff) models where the best-worst pair is the unit of analysis, and sequential best worst multinomial logit models where the attribute level is the unit of analysis.[18 19] Preference heterogeneity will be investigated via covariate-adjusted regression as well as random parameter versions of these models and scale-adjusted latent class analyses. Values will be obtained for all possible states defined by the descriptive system using the marginal sequential or paired (maxdiff) model suggested by the BWS data. The explanatory power of the two BWS models is likely to be similar. The marginal sequential model will be utilised when investigating heterogeneity in preferences, given its support in major statistical packages including Stata and Latent Gold.[22 23]

The estimates from the BWS task are initially anchored to the least valued attribute level. Since these estimates are on an interval scale, a linear transformation can be applied in order that the best state takes the value one and the 'PITS' state (the state comprising the lowest level on each of the attributes of the descriptive system) takes the value 0. However, in order for the estimates to have QALY properties for application within economic evaluation 0 must represent the state 'dead', not the PITS state. One method of achieving this involves administering a traditional DCE where length of life is included as an additional attribute. This would necessarily involve the presentation of many states for valuation and a complex choice task, which is a concern among an older population. An alternative method involves rescaling the estimates using the results obtained from a second choice task. This can be achieved (mathematically and conceptually) by using the most severe or PITS state value from a time trade off or standard gamble exercise to rescale the original estimates to ensure that the 0 represents dead.[23 24]

We will elicit a PITS state value for re-scaling, via a time trade off exercise. This will be undertaken with a sub sample of older people without cognitive impairment (defined according to a MMSE score of 24 or above) who consent to participate in a follow-up study via an interview. Previous health state valuation exercises have indicated a time trade off task is generally easier for respondents to understand and complete than standard gamble and direct valuation by a sub sample of older people with good cognitive functioning will be feasible.[5] Previous research has also indicated that a relatively small sample size of n=40 will be sufficient to ensure precise estimation of the PITS state value.[23 24] The values elicited from the time trade off task will be utilised to rescale the BWS estimates to ensure that the 0 represents dead, rather than the utility of the most severe state. The resulting scoring algorithm will then be applicable to generate values for all quality of life states defined by the new quality of life instrument.

Following the development of the new quality of life instrument, the relationships between the new quality of life instrument and the EQ-5D-3L and the EQ-5D-5L will be investigated.[26 27] Mapping algorithm will also be developed using recommended best practice methods[28] to facilitate the estimation of reweighted utility values from existing data sets incorporating the EQ-5D-3L or the EQ-5D-5L.

ETHICS AND DISSEMINATION

A project steering committee, consisting of key stakeholders and including consumer representatives will provide congruency across the project in relation to the development of the new quality of life instrument. The steering committee will meet quarterly throughout the project's duration to advise on the development of the new descriptive system, its practical implementation and provide feedback. This project will directly address the limitations of existing instruments by incorporating the preferences and values of older people into the first generic preference based instrument, developed exclusively from its inception with older people, for the calculation of QALYs for economic evaluation. The new quality of life instrument will have wide applicability in Australia and internationally for assessing the cost effectiveness of new service innovations and for quality assessment across the spectrum of ageing and aged care.

Information about the project and its findings will be communicated to the aged care sector and the general community via the participating organisations' external relations units targeting local, state and national web, print and electronic media. In addition, the results of the project will be disseminated at international conferences and published in academic journals. A website will be developed to facilitate access to the new quality of life instrument and for publishing outcomes and key findings from the project for participants, their families and the general public.

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