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Identification of core outcomes for quality in routine care provided to people living with dementia in Australia: a multilevel modified Delphi consensus study

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ABSTRACT

Objective To co-design a core outcome set with people living with dementia and other stakeholders that can be used to measure the quality of dementia care in home care and residential settings.

Design Multilevel modified Delphi consensus study. A priori consensus threshold of 70% was used to include or exclude outcomes.

Setting Routine dementia care provided through home care and residential aged care facilities in Australia.

Participants A stakeholder panel comprising people living with dementia, formal and family/informal carers of people living with dementia, advocates, policy experts, allied-health professionals, nurses and professionals working in the aged care industry. Round 1 included 10 panellists; subsequent rounds extended the number of participants to 24.

Results Seven outcome domains (Death, Physiological and clinical, Functional, Life impact, Resources, Adverse events and Education), encompassing 105 individual outcomes were considered by the panel over four rounds.

The 105 outcomes were distilled to 16 outcomes identified as important in home care and 15 in residential aged care. In both settings, nine outcomes (Dignity, Advanced care planning, Meaningful activities, Feeling safe and secure, Emotional wellbeing, Quality of Life, Resource utilisation, Safety incidents and Dementia-specific qualifications for care staff) were considered important.

Additionally, seven outcomes in the home care setting (Behavioural symptoms of dementia, Diagnosis of dementia, Hygiene, Importance of Relationships, Quality of carer and family lives, Dementia care navigation and Opportunities for unpaid carers) and six outcomes in the residential aged care setting (Neuropsychiatric symptoms of dementia, Pain, Hygiene and comfort, Medication safety, Staff carer morale and Adverse effects) were classified as important.

Conclusions The outcomes identified during this modified Delphi consensus study provide a promising basis for the development of a meaningful, practical and measurable core outcome set that could be used in dementia care

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Co-designed with people living with dementia.
⇒ Multistakeholder engagement and transparent reporting.
⇒ Flexible and adaptive in response to the needs of participants.
⇒ Declining response rates over time.
⇒ No final input from policy makers.

settings to improve the quality of routine care provided to people living with dementia.

BACKGROUND
Purpose

The purpose of this consensus process was to identify core outcomes appropriate for evaluating the quality of routine care provided to people living with dementia in either home care or residential care settings.[1] Using this approach, we aim to expand the knowledge base of outcome measures by providing insight into what outcomes people receiving and providing dementia care consider essential features of quality care.

Rationale

Dementia is a term used to describe symptoms of a number of different neurodegenerative conditions that progressively impair a person's memory, thinking and brain function, impacting their ability to perform everyday activities.[2] There are currently no disease-modifying treatments for dementia, and the risk of developing dementia accelerates with increasing age. In 2023, the Australian Institute for Health and Welfare estimated the prevalence of dementia at 15 Australians per 1000, increasing to 84

per 1000 in Australians aged over 65.[3] While an ageing population will increase the prevalence of dementia and its associated health burdens, little is known about the perceptions and preferences of stakeholders in dementia care, or what outcomes are relevant and meaningful for people living with dementia, their carers and families, or their networks of care support.

The 2020 Australian Royal Commission into Aged Care Quality and Safety found large deficits in the quality of care provided to older Australians, particularly those living with dementia, across all care settings.[4] The reforms arising from the Royal Commission's recommendations, detailed in the final report, have created a sizeable shift in approaches to care in Australia to ensure vulnerable older people receive care that affords dignity, respect and freedom of choice. Dementia is a key target area for reform, with interventions developed that target support for people living with dementia and their carers from initial diagnosis through to later disease stage. While the Royal Commission's recommendations in the final report define the goals of quality dementia care and the scope of change required to achieve them, the monitoring and evaluation framework required to ensure new interventions are improving the quality of care remains unclear.

Core outcome sets (COS) are instruments designed to ensure transparency, comparability and efficiency in measuring significant outcomes in research.[5] COS are increasingly being used in healthcare as a way to monitor and evaluate healthcare systems, as they provide a standardised approach that reduces heterogeneity and thus promotes fair comparisons based on the most essential outcomes.[6] Historically, COS were developed for use in clinical trials and used to address specific research objectives over finite time horizons. The Core Outcome Measures in Effectiveness Trials (COMET) initiative, launched in 2010, systematically collates and synthesises COS appropriate for a wide variety of health settings, with a focus on improving standards of reporting and

data synthesis in health trials.[7] The adaptability of COS to routine healthcare and potential suitability for ongoing health system monitoring and evaluation are uncertain. The Core Outcome Measures for Improving Care (COM-IC) project is a 2-year Medical Research Future Fund (MRFF)-funded project that aims to develop and implement a core outcome set for routine care provided to people living with dementia in Australia, developed using embedded participatory action research methods within the Alignment-Harmonisation-Results framework.[1] This paper is a component of the COM-IC project that focuses on the design and implementation of a multilevel modified Delphi approach applied to a hierarchy of outcomes to reach consensus on the core outcomes that are meaningful and relevant to people living with dementia and their carers and families.

METHODS

Study design

Delphi methodology uses rounds of surveys and discussions to systematically and transparently build consensus on a topic of mutual expertise.[8] A modified Delphi process was chosen as a systematic methodology to support discussion and resource sharing among stakeholders and as a reliable way to collect data pertaining to beliefs and preferences, ensuring the outcomes selected reflect what is meaningful and relevant to stakeholders impacted by the care of people living with dementia.[9] We adapted the Delphi methodology for the COM-IC project to progress stakeholders through a hierarchy of decisions each round (figure 1). Consensus was reached first on the most important domains of quality care, then the most important categories of quality in each domain, and then the most important outcomes in each category. The starting domains and outcomes were drawn from an extensive literature review of core outcome sets for routine care,[10] with subsequent extraction of a subset
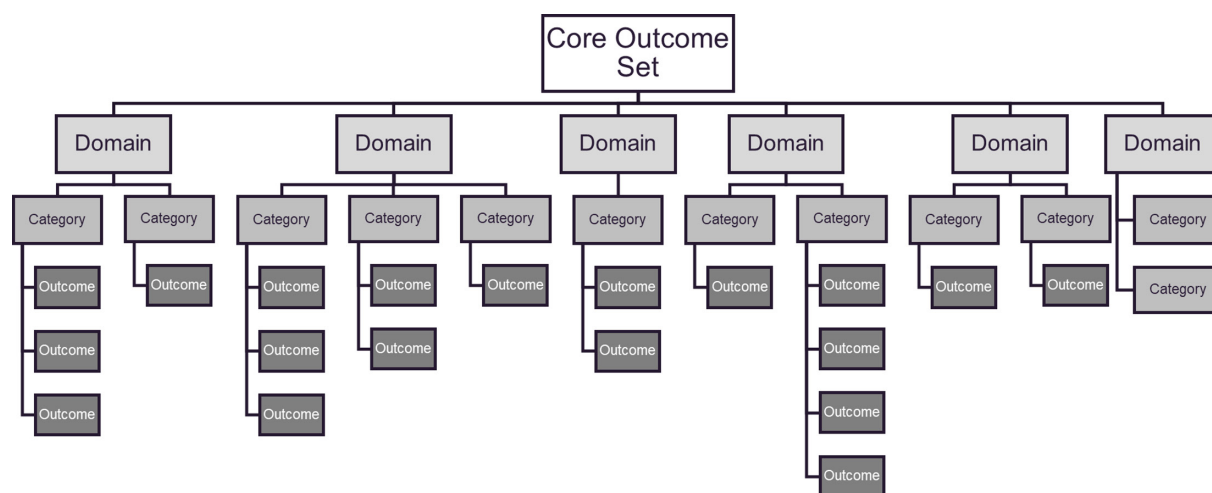
Figure 1 Decision hierarchy for Delphi design. The Core Outcome Measures in Effectiveness Trials outcome taxonomy was used to structure outcomes and reduce decision fatigue for panellists when considering appropriate domains and outcomes for inclusion by importance.

where core outcome sets were described specifically for people living with dementia.

The modified Delphi design incorporated four rounds of surveys administered through Qualtrics using individually unique email links. The Delphi panel was originally comprised of the Stakeholder Reference Group (SRG), but expanded in round 2 to facilitate a broader and more nuanced understanding of outcomes important to people living with dementia. Panellists were asked to consider outcomes in two aged care settings, home care and residential aged care, where most people living with dementia access routine care services.[3] Outcomes of importance were considered separately for these care settings to establish commonalities or differences between the settings, and in recognition of the role of informal carers and family in home care settings.

Each round remained open to responses for a minimum of 2 weeks, with weekly reminders emailed to panellists with responses not yet submitted. All panellists were offered support to complete their survey, and survey deadlines were extended for participants who required extra time to manage the cognitive demands of the survey instrument. Each round built on the previous round, adjusting the survey instrument each round in response to feedback and interim discussions arising from the preceding round/s.

Between survey rounds, panellists discussed the results of previous rounds using a combination of online asynchronous (text-based) and synchronous digital platforms, including Zoom, Loomio and Microsoft suite. Examples of activities with these platforms include informal online drop-in sessions (Zoom), documented reports of outcomes of survey round (Microsoft Word), discussion forums (Loomio), document sharing (Microsoft OneDrive) and newsletters (Microsoft Outlook). Through these options, panellists were encouraged to share resources and constructively discuss points of interest or aspects that presented challenges completing each round of the Delphi consensus process. Each round built on the previous round, with questions which were adjusted in response to feedback and interim discussions arising from the preceding round/s.

Analysis involved both quantitative and qualitative methods and was conducted by the project manager (DK), who then collated and distributed the results to the panel for discussion prior to the next round.

Participants
The COM-IC project is a co-designed programme of research aiming to develop a COS suitable for use in routine care settings where care is provided to people living with dementia, detailed in the protocol published in *BMJ*.[1] This Delphi consensus activity is a component of the broader COM-IC project involving the SRG, a representative group of people with lived experience of dementia who provide advice and support to the co-design elements of the COM-IC research programme.

The COM-IC SRG was established in two parts: the representative SRG and associate SRG. The representative SRG was established through a recruitment process, including advertisement through dementia support networks, selection and screening of appropriate candidates and offer of appointment. These positions were remunerated based on time commitments, including reading, preparation of advice/feedback and attendance at SRG events. The representative SRG consisted of 10 individuals across Australia who demonstrate experiences in having dementia, using dementia care services, being impacted by dementia, or providing care for people living with dementia. The composition of the representative SRG is shown in online supplemental table 1.

Acknowledging the breadth and depth of the community network to be consulted regarding dementia care, as well as the knowledge and experience of the Australian dementia care network, the option to extend the reference group, using the associate SRG designation, for specific activities was inbuilt into the SRG terms of reference and subsequently actioned for round 2. We collectively refer to this combined group of core SRG and associate SRG members for this activity as the 'extended Delphi panel' and further refer to the combined group members as 'panellists'. Panel composition is shown in online supplemental table 1.

The SRG was tasked with selecting the most relevant and meaningful outcomes for stakeholders. After careful consideration of the fairest and most transparent way to reach a consensus, the SRG considered the Delphi method to be the most robust. Accordingly, the process is reported in keeping with the Accurate Consensus Reporting Document checklist.[11]

Pre-survey and preparation
As the SRG were drawn from a population with assumed low level knowledge of core outcome measurement, a series of educational activities and consultations with outcome measures experts from the COM-IC investigator team (PW, SD, AK, DT) provided an introduction to core outcomes via a series of educational activities undertaken, including general meetings, online discussion boards, introductory slide presentation describing outcome measurement, links to COMET and YouTube videos explaining core outcomes, and an introduction to core outcome taxonomy as defined by COMET and used by the Cochrane collaboration.[12] A large systematic review of core outcome sets used in routine care was subset for dementia-specific COS.[10] The extraction tables have been included in online supplemental tables 2 and 3. These tables were cross-checked with an internal University of Queensland (UQ) review that confirmed the extraction contained all papers related to dementia COS currently adopted for routine care.

Round 1: domain selection
The round 1 (domains) survey was distributed to ten members of the COM-IC SRG. They were tasked with

ranking the importance of six outcome domains on a 5-point Likert scale across home and residential aged care settings that had been identified in previous research as being core in routine dementia care. Panellists were also asked to rank the domains by importance and to identify any domains they felt were core but missing. Each question included free-text entry options for panellists to share thoughts, opinions and perspectives that influenced their choice. Domains ranked as important or very important by ≥70% of panellists met the threshold for consensus and were retained; domains ranked as 'not at all important' and 'slightly important' by ≥70% met the exclusion threshold and were excluded from further rounds. Items considered only 'moderately important', or those that did not reach either threshold, were returned for further discussion.

Round 2: outcome category selection

The round 2 (outcome categories) survey built on results and feedback from round 1. The panel was expanded to include a greater diversity of thought and to include the voice of more people living with a diagnosis of dementia. An additional domain identified in round 1 was incorporated. For this round, panellists were asked to assign an importance ranking to 22 outcome categories across seven outcome domains. A 5-point Likert scale was used by panellists to rank each outcome category according to care setting, separating home care and residential aged care. All domains included free-text entry options for panellists to share thoughts, opinions and perspectives that influenced their choice. The final question of the survey invited panellists to share outcomes they considered important that were not included in the survey. Outcome categories ranked as important or very important by ≥70% of panellists were retained; domains ranked as 'not at all important' and 'slightly important' by ≥70% were excluded from further rounds. Items considered only 'moderately important', or those that did not reach either consensus threshold, were returned for further discussion.

Round 3: outcome selection

The round 3 (outcomes) survey extended the survey instrument to include outcomes within the outcome categories that achieved consensus in the round 2 survey. The survey design was modified based on discussions with panel members. Panellists in round 3 were asked to select the top 20% of outcomes in each domain they considered most important. Panellists considered 96 outcomes across seven domains. This modification was made to force a choice and converge the outcome set on factors that are most important to stakeholders. Outcomes selected by ≥70% of panellists were recommended as core outcomes, outcomes selected by ≤30% of panellists were excluded from further rounds and outcomes selected by 31%–69% of panellists were referred for further discussion. All domains included a free-text entry option for panellists

to share thoughts, opinions and perspectives that influenced their choice.

Round 4: outcomes

The round 3 survey did not achieve consensus on the most important outcomes. The round 4 (outcomes) survey design was modified based on discussions with panel members. The survey asked panellists to select up to 6 outcomes from a list of 23 outcomes they thought should be retained for inclusion in a core outcome set. Outcomes were not nested within domains due to unequal numbers of outcomes that produced unfair weighting penalties, and based on feedback that some outcomes applied to more than one domain. One free-text entry option was included for panellists to share thoughts, opinions and perspectives that influenced their choice.

Final consensus

Round 4 (outcomes) results were drafted and circulated in a final report, with panellists providing written confirmation over email accepting the recommended outcomes, which would inform working groups dedicated to identifying the best measures for the identified outcomes.

Data analysis

Survey responses were downloaded from Qualtrics to Microsoft Excel. Excel and Word were used to generate reports at the conclusion of each round. Reports contained response rates, Likert scale distributions and summaries of free-text responses. Reports were distributed to panellists and used to support consensus discussions.

Patient and public involvement

The COM-IC project maintains a strong focus on participatory action research methods, involving dementia care stakeholders in every aspect from initial concept design to publication and distribution of results. This consensus process was designed by and conducted with an SRG, expanding to accommodate additional stakeholder insight with the creation of the Stakeholder Panel (SP). The involvement and engagement of stakeholders are described through the Methods section, in the protocol paper and in Standardised Data on Initiatives (STARDIT) reports.[1 13] The outcomes suggested for improving care from this research are generated entirely from contributions of the SRG and broader SP.

The Delphi consensus process was selected as the most appropriate way to achieve consensus by the SRG. The SRG communicates both synchronously and asynchronously, through quarterly meetings, weekly virtual drop-in sessions, weekly email updates and ongoing contributions to discussions on Loomio. The SRG completed the first round and subsequently voted to increase stakeholder input, creating a broader stakeholder panel for the remaining rounds. Separate discussion threads and drop-in sessions were created to support decision-making efforts of the SP for the duration of their engagement.

From inception, the COM-IC project has captured every aspect of the research programme using

STARDIT,[13] recording responsibility and contributions of all project members. The STARDIT report about the COM-IC project is publicly accessible and can be updated over time as more impacts and outcomes from the project emerge (https://stardit.wikimedia.org.au/wiki/0202208100258). Using STARDIT provides for truly embedding patient and public participation through all aspects of the research project and beyond.

RESULTS

The COM-IC Delphi panel reached consensus over four rounds on 16 outcomes essential to measure in home care and 15 outcomes essential to measure in residential aged care settings that should be included in a core outcome set designed to measure quality of routine care provided for people living with dementia in these settings. The consensus process and outcomes of each round are described in figure 2.

Pre-survey

The SRG used their new knowledge from COMET and the COM-IC investigators to identify suitable outcomes for inclusion. With support from the COM-IC investigators (DK, T-HD-T, TM, JL, AM, PW, AK, SD), the SRG conducted a gap analysis from industry reports and existing systematic reviews of core outcome sets used in routine care. Results of the scoping activities are presented in online supplemental table 4. Following the COMET taxonomy, a starting table of outcome measures nested within domains formed the foundation of the survey instrument.
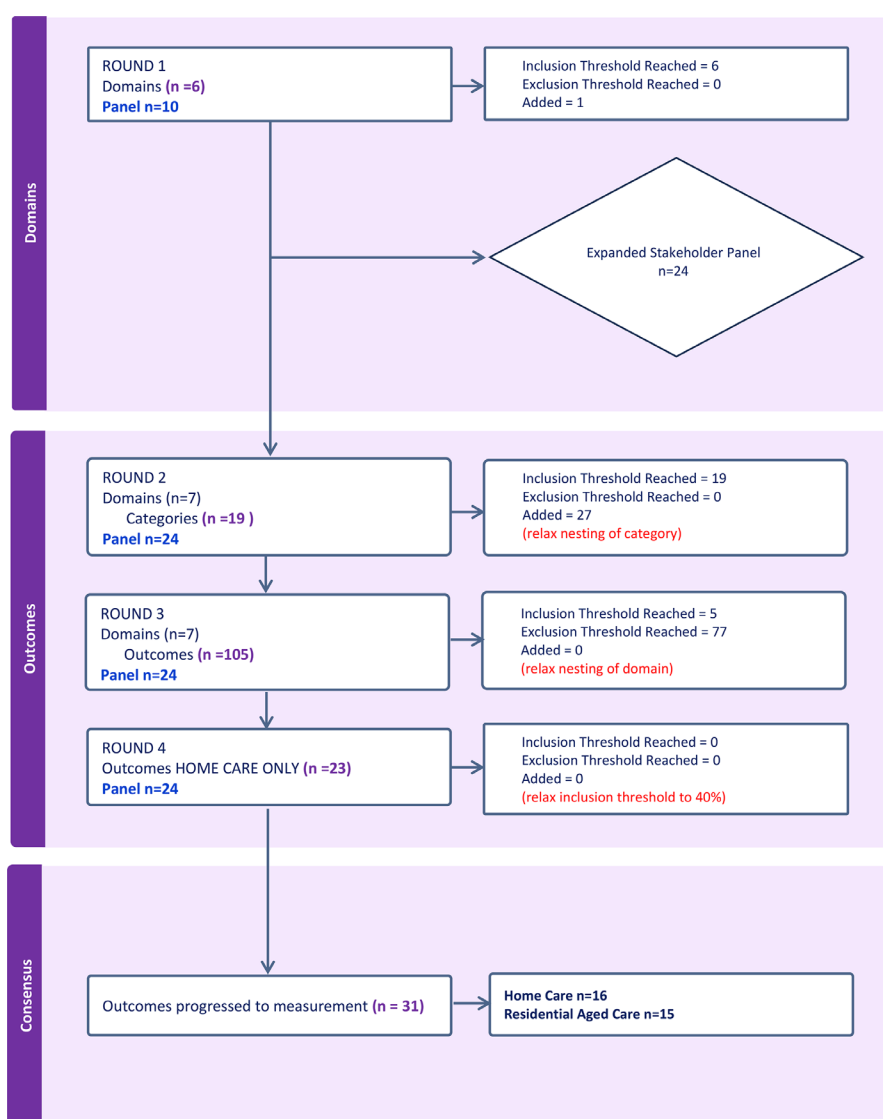
Figure 2 Core Outcome Measures for Improving Care Delphi panel consensus flow diagram. A modified Delphi consensus process with interim adjustments to the consensus instrument based on panel discussions was selected through co-design as the best method to reach agreement on core outcome measures that are important and meaningful to people living with dementia. The process evolved over four rounds and produced a list of outcomes which will be workshopped for appropriate measures and inclusion in a core outcome set appropriate for use in routine care settings where people living with dementia receive services.

Table 1 Round 1 consensus results

Domain	Home care		Residential care	
	Important or very important	Ranking	Important or very important	Ranking
Death	77.7%	6	77.7%	6
Physiological/clinical	87.5%	2	87.5%	3
Functional	100%	1	100%	1
Life impact	100%	3	100%	4
Resources	100%	4	100%	2
Adverse events	100%	5	100%	5

Round 1 (domains)

The round 1 (domains) survey was distributed to the SRG in September 2023. Panellists were asked to rate the importance of six domains relevant to the quality of routine care provided to people living with dementia: death, physiological/clinical, functional, other life impact, resources and adverse events. Panellists were invited to share thoughts, opinions and perspectives that influenced their choices. Details of the panel composition and respondents are available in online supplemental table 5.1.

Of the 10 SRG members invited to complete the survey, 8 provided a response. All domains met the consensus threshold for inclusion in a COS for routine care provided to people living with dementia in both home care and residential aged care settings (table 1). Functional outcomes and adverse events were considered the most important, with 87.5% of respondents indicating that these outcome domains were very important in both care settings. Resource use was also rated very important in residential aged care by 87.5% of respondents. The domain of death was considered only moderately important by 22.2% of respondents, and physiological outcomes were considered only moderately important by 12.5% of respondents. When asked to rank domains in order of importance, functional outcomes were considered the most important and death the least important in both care settings. Feedback during panel discussions indicated that the different rankings assigned to domains in different care settings reflect the impact of the level of functional loss and changes in care needs between the settings, as well as the different role carers and family members play in each setting.

An additional domain, education, was identified as a gap in the quality domains. The education domain was defined as including workforce preparedness and support for people receiving care, and categories of education were identified for inclusion in future survey rounds.

Panel discussions and modifications to the consensus instrument

Results of the round 1 survey were distributed to the SRG via email, and discussion of results was facilitated using established communication channels. The SRG raised concerns that their input alone would not be robust to reach consensus on outcomes that were meaningful to a broader group of people living with dementia. The Delphi panel was consequently expanded to incorporate an additional 14 people impacted by dementia (2 people with dementia and 12 carers) through a further recruitment process.

Round 2 (outcome categories)

The round 2 survey was distributed to 24 SP members in November 2023 and closed in December 2023. It presented outcome categories nested within the seven identified domains (death, physiological, functional, other life impact, resource use, adverse events and education) and asked panellists to rate the importance of each outcome category in home care and residential aged care settings. Panellists were invited to share thoughts, opinions and perspectives that influenced their choices. Details of the panel composition and respondents are available in online supplemental table 5.2.

As education does not currently fall within the existing COMET taxonomy, the outcome categories included in the education domain were developed by panel members during the review of round 1 survey results. Panellists were asked to nominate whether education should be a separate domain or an outcome category nested within an existing domain.

Of the 24 panellists invited to complete the survey, 22 attempted a response. All outcome categories met the inclusion threshold (table 2). Eye health and mortality were considered the least important categories in both care settings.

Education was considered a separate domain by the majority of panellists, though some remained of the opinion that education outcomes should be nested across every domain. All four categories met the threshold for inclusion and several additional outcomes were identified by panellists as potential gaps for inclusion in future survey rounds. The outcomes suggested by panellists were the following:

► Advanced care planning.
► Legal Outcomes (esp end of life, power of attorney etc).
► Length of life, weighted by quality.
► Person-reported outcome measures.
► Emotional well-being.
► Dignity.

Table 2 Round 2 (outcome categories) consensus

Domain	Outcome category	Home care (%)	Residential care (%)
Death	Mortality	74	79
Physiological/clinical	Eye	67	72
	Injury and poisoning	83	94
	Nervous system	100	100
	Psychiatric	100	100
Functional	Physical	100	100
	Social	82	94
	Emotional	100	94
	Cognitive	100	100
Life impact	Global quality of life	88	88
	Delivery of care	94	94
Resources	Economic	76	82
	Hospital	82	82
	Societal and carer burden	100	88
Adverse events	Adverse events	88	89
Education	Dementia-specific professional development	88	94
	Care planning with dementia consultant	94	100
	Family engagement in learning	100	88
	Use of dementia education services	94	100

► Goal setting.
► Functional capacity.
► Risk assessment.
► Physical environment.
► Safety alarms.
► Managing expectations.
► Pain management.
► Hygiene.
► Skin care/skin integrity.
► Dental care.
► Nutrition.
► Psychological outcomes, as distinct from psychiatric.
► Quality of carer and family lives, distinct from the person with the diagnosis.
► Dementia care navigation.
► Accessibility to participation in clinical trials and appropriate research.
► Medication-related adverse events.
► Injuries/harm secondary to unsafe environment.
► Psychological harm caused by others.
► Physical harm caused by others.
► Neglect.
► Complaints management (acknowledgement and response).

Panel discussions and modifications to the consensus instrument

Results of the round 2 survey were distributed to all panel members via email, and discussion of results was facilitated using established communication channels. Panellists indicated diminished comprehensiveness when considering only outcome categories, so outcome categories were expanded to present outcomes nested within the categories, consequently removing the categories from the consensus instrument. The round 2 survey and subsequent discussions did not significantly reduce the number of outcome categories to be carried into the round 3 survey. Consequently, changes to the consensus approach for the round 3 survey were agreed in consultation with panellists. In response to the need to converge over 100 outcomes into a concentrated core outcome set, the survey instrument was modified to force a trade-off, by asking panellists to choose 20% of outcomes in each domain that they consider 'most important'.

Round 3 (outcomes by domain)

The round 3 (outcomes by domain) survey was distributed to 24 panellists in January 2024 and closed in February 2024. It presented 105 nested outcomes (including those identified in round 2 as potential gaps) within seven domains and asked panellists to choose the most important outcomes, with the maximum number of outcomes limited to 20% of those in each domain and in each care setting. Panellists were invited to share thoughts, opinions and perspectives that influenced their choices. Details of the panel composition and respondents are available in online supplemental table 5.3.

Of the 24 panellists invited to complete the survey, 19 provided a response. The percentage of panellists who included a particular outcome in their top 20% is shown in table 3. Six outcomes in residential aged care and one outcome in home care met the inclusion threshold.

Table 3	Round 3 consensus results		
Domain	**Outcome**	**Home care (%)**	**Residential care (%)**
Met inclusion threshold			
Functional	Meaningful activities	71	76
	Hygiene and comfort	*41*	71
	Feeling safe and secure	*53*	76
	Emotional well-being	*59*	71
Resource use	Staff carer morale	*6*	76
Education	Dementia-specific qualifications for service provider	*59*	76
Did not meet inclusion threshold			
Death	Mortality	0	6
	Advanced care planning	39	29
	Legal outcomes	0	0
	Length of life	6	0
	Dignity	50	59
	Cause of death	6	6
Physiological	Vision	6	6
	Hearing	6	6
	Injury	12	18
	Poisoning	0	0
	Falls	18	35
	Biological markers	0	0
	Behavioural symptoms of dementia	41	29
	Neuropsychiatric symptoms of dementia	29	41
	Behaviour	6	24
	Onset of behavioural disorders	6	0
	Comorbidities	29	6
	Oral health	0	6
	Diagnosis of dementia	41	12
	Psychological outcomes	29	29
	Pain	29	41
	Hygiene	41	29
	Skin care/skin integrity	6	12
Functional	Doing what you can do	29	24
	Falls prevention	47	41
	Staying healthy and fit	29	6
	Walking better	12	12
	Being able to stand up and climb stairs	0	0
	Hygiene and comfort	41	*71*
	Stability	6	6
	Activities of daily living	41	18
	Instrumental activities of daily living	6	0
	Functional capacity	6	6
	Functional ability and independence	24	24
	Importance of relationships	53	41
	Communication	24	24
	Social	18	12
	Role functioning	12	6

Continued

Table 3 Continued

Domain	Outcome	Home care (%)	Residential care (%)
	Feeling safe and secure	53	*76*
	Feeling valued and respected	12	41
	Apathy/indifference	6	6
	Self-managing dementia symptoms	6	0
	Having a laugh	6	0
	Patient mood	0	6
	Enjoying the moment	12	6
	Feeling brighter	6	0
	Feeling useful and having a purpose	47	24
	Alertness	0	0
	Understanding time and place	12	6
	A sense of who you are	24	12
	Global assessment	0	6
	Disease progression	6	6
	Time to reach value on incapacity scale	0	0
	Cognition/executive capacity	18	12
	Person-reported outcome measures	0	0
	Emotional well-being	59	71
	Managing expectations	6	12
Other Life Impact	Quality of life	59	53
	Well-being	41	47
	Person with dementia health-related quality of life	24	41
	Perceived health status	0	6
	Medication appropriateness	41	53
	Acceptability (of intervention) to client	18	18
	Acceptability (of intervention) to informal carers	6	6
	Acceptability (of intervention) to Stakeholders	0	0
	Satisfaction	6	12
	Inter-professional collaboration	29	12
	Personal circumstances	6	18
	Goal setting	6	6
	Risk assessment	12	24
	Physical environment	12	12
	Safety and security	35	35
	Quality of carer and family lives	53	12
	Dementia care navigation	35	6
	Accessibility and engagement in clinical trials	0	6
	Neglect	6	12
	Complaints management (incl. response)	12	18

Continued

Table 3 Continued

Domain	Outcome	Home care (%)	Residential care (%)
Resource Use	Resource utilisation	65	65
	Health economic measures (QALY)	6	12
	Hospital admission	6	24
	Need for further intervention	24	35
	Family carer burden	47	6
	Staff carer morale	6	*76*
	Family/carer quality of life	59	12
	Carer mood	12	12
	Reaction to behaviour	12	47
	Full-time care	18	0
	Entry to institutional care	18	6
	Need for home help	29	6
Adverse Events	Medication side effects	12	18
	Adverse drug events	6	6
	Adverse effects	18	24
	Safety incidents	41	24
	Physical harm caused by others	12	12
	Medication-related adverse events	12	18
Education	Dementia-specific qualifications for service provider	59	*76*
	PD framework including caring for people with dementia	18	35
	Provision of PD opportunities	18	24
	Accessibility to educational materials	0	6
	Support to process diagnosis	24	0
	Access to dementia-specific educational services	24	24
	Mentoring and peer supervision opportunities	6	24
	Opportunities for unpaid carers and family	47	12
	Self-assessed confidence to provide care	6	0

PD, Professional Development; QALY, Quality Adjusted Life Year.

80 home care outcomes and 83 residential aged care outcomes met the exclusion threshold.

Panel discussions and modifications to the consensus instrument

Results of the round 3 survey were distributed to all panel members via email, and discussion of results was facilitated using established communication channels. Panel discussions centred on the adequacy of the inclusion threshold and whether a subsequent round was needed to move closer to consensus on outcomes ranked highly by between 31% and 69% of participants. Panellists also queried the need to include an outcome from each of the seven domains previously considered important, and subsequently including the top-ranked outcomes from each domain. In a polling vote, the panel was divided over accepting top-ranked outcomes or completing another round. Panellists were encouraged to consider how the significance of particular outcomes might change when they were presented to working groups to identify relevant measures.

Due to uncertainty over the best approach, a further survey was developed and distributed to reach closer consensus on outcomes.

Round 4 (outcomes)

The round 4 (outcomes) survey was distributed to 24 panellists in March 2024 and concluded in April 2024. Details of the panel composition and respondents are available in online supplemental table 5.4. It presented only the 23 undecided outcomes from round 3 that were considered important by between 31% and 69% of participants. The round 4 survey only asked panellists to rate the importance of outcomes for the home care setting, where there was the highest divergence of consensus in the round 3 survey. Due to the unbalanced distribution of outcomes across categories and domains, outcomes were considered as standalone. Panellists were asked to identify the most important 20% (five outcomes) of the 23 possible outcomes and were invited to share thoughts, opinions and perspectives that influenced their choices.

Table 4 Outcomes from round 4 and comparative percentage with round 3

Outcome	Round 4 (%)	Round 3 (%)
Advanced care planning	13	39
Dignity	47	50
Behavioural symptoms of dementia	20	41
Diagnosis of dementia	33	41
Hygiene	7	41
Falls prevention	33	18
Hygiene and comfort	20	41
Activities of daily living	27	41
Feeling safe and secure	20	53
Feeling useful and having a purpose	33	47
Emotional well-being	27	59
Quality of life	47	59
Well-being	13	41
Medication appropriateness	27	41
Safety and security	20	35
Importance of relationships	20	53
Dementia care navigation	40	35
Resource utilisation	7	65
Family/carer burden	20	47
Family/carer quality of life	47	59
Safety incidents	7	41
Dementia-specific qualifications for service provider	60	59
Education opportunities for unpaid carers and family	13	47

Of the 24 panellists invited to complete the survey, 15 provided a response. None of the outcomes reached the consensus threshold for inclusion in the core outcome set, and most outcomes were selected by a lower proportion of panellists than in the previous round (table 4).

Panel discussions

Results of the round 4 survey were distributed to all panel members via email, and discussion of results was facilitated using established communication channels. Panellists were asked their preferences on progressing only the items that reached consensus in round 3 (outcomes by domain) in the core outcome set, or including outcomes that scored above 40% in the round 4 survey. All panellists expressed a preference to respect the priorities of other panel members and include any outcomes that did not satisfy the exclusion criteria (not selected in 70% or more of responses).

Conclusions and final decision

Post-survey analysis and discussion identified the top ranked outcomes from round 3 (outcomes by domain) were most appropriate for inclusion in the core outcome set. Relaxing the upper limit of the inclusion threshold to include all outcomes from round 3 that did not meet the exclusion threshold (not selected by 70% or more responses), the final outcome sets recommended for measurement working groups are presented in table 5.

DISCUSSION

The COM-IC project engaged dementia care stakeholders to co-design and execute a modified Delphi consensus process, producing a list of outcomes considered most important for measuring the quality of routine care provided to people living with dementia in Australian aged care settings.[1] Based on an international scoping

Table 5 Recommended core outcomes consensus

Area	Home care	Residential aged care
Death	Dignity Advanced care planning	Dignity Advanced care planning
Physiological	Behavioural symptoms of dementia Diagnosis of dementia Hygiene	Neuropsychiatric symptoms of dementia Pain
Functional	Meaningful activities Importance of relationships Feeling safe and secure Emotional well-being	Meaningful activities Hygiene and comfort Feeling safe and secure Emotional well-being
Other life impact	Quality of life Family/carer quality of life	Quality of life Medication appropriateness
Resource use	Resource utilisation Dementia care navigation	Staff carer morale Resource utilisation
Adverse events	Safety incidents	Safety incidents Adverse effects
Education	Dementia-specific qualifications Opportunities for unpaid carers	Dementia-specific qualifications

review of existing core outcome sets used in research, a preliminary list of six domains formed the foundation of the consensus process.[10] Core outcome sets are traditionally and effectively used in research trials, so there is reason to consider their transferability to routine care.[5] The Delphi process used in this project has revealed that different care settings and different time horizons result in different outcomes of significance, reflecting the differing structures and objectives of research trials and routine care, as well as the nature and priorities of care provided in different settings. The project also identified a broader scope of outcomes relevant to routine care than those used in clinical trials, which often focus on achieving specific outcomes.

Delphi consensus methodology provides for substantial flexibility, and the COM-IC Delphi panel used this to full advantage. The expansion of the Delphi panel from 10 to 24 people prior to the round 2 survey was essential to achieving meaningful consensus on outcomes of importance for people living with dementia. The complexity of the decisions required and the interrelationships between aspects of quality proved a challenge to the panel and facilitators in maintaining clarity over outcomes, categories, domains and the definitions. The panel dedicated considerable time to the competing priorities of respecting the views and priorities of all members, while acknowledging the infeasibility of a core outcome set with too many outcomes. Nevertheless, the panel identified significant gaps in the outcomes used to measure clinical research compared with routine care.

The significance and inclusion of the Education domain are notable, particularly in view of this domain being absent from the COMET taxonomy. While predominantly reflecting the longer time horizon of routine care and the multivariable nature of practical, real-world application, the value of knowledge to quality care cannot be overstated, and stakeholders are in agreement that the Education domain is critical to quality of care. Recognition is also afforded to the idea that knowledge and capacity to provide appropriate care extend beyond an initial formal qualification, acknowledging that formal qualifications in dementia care when providing care for a person living with dementia would be a positive first step.

The deep engagement of panel members and commitment of both panellists and the research team to collaborative design supported a Delphi process that evolved to meet the needs of both groups. Sufficient time and opportunity were available for panellists to meaningfully contribute to decisions and discussions, and the design of each survey was geared towards achieving consensus—the overall objective of the research. Notwithstanding, reaching consensus was difficult, with comparatively few outcomes included in the top 20% by more than 70% of panellists. The trade-off was a necessary modification as panellists expressed reluctance to exclude any outcomes, recognising the complexity of what constitutes quality care. There is genuine fear among stakeholders that the omission of an outcome from the core outcome set will result in that aspect of care being largely ignored, and all of the identified areas of care are important.

Engagement in meaningful activities was the only outcome to reach the 70% inclusion threshold for home care. Seven outcomes achieved this threshold in the residential aged care setting: engagement in meaningful activities, hygiene and comfort, feeling safe and secure, emotional well-being, staff/carer morale and dementia-specific qualifications for care staff. Notable absences were quality of life and physical outcomes such as activities of daily living, which are both currently outcomes of interest for service providers. It is possible that the relative importance of these outcomes is reduced by their prevalence, while outcomes not currently measured are more obvious gaps.

An additional Delphi round did not achieve consensus on additional outcome measures for home care, with 23 outcomes considered important but not meeting the consensus threshold. This result underscores the persistent uncertainty around a collective definition of core outcomes and reflects the heterogeneity of needs across stakeholder groups in healthcare. The general preference of the panel is to consider a wider set of outcomes when identifying potential measures in the next phase of the project.

Strengths and limitations

The main strengths of this research include the diversity of stakeholder input, the inclusion of people living with dementia in decisions about their care, consideration for transferring research into practice, the collaborative approach to building consensus, and the flexibility of the Delphi method. The combination of these features has generated a COS that is meaningful and relevant for people impacted by dementia in everyday contexts. This COS represents an opportunity to measure the quality of care in routine dementia care settings, facilitating the identification of opportunities to improve health outcomes, reduce adverse health events and optimise resource use through provision of consistent, comparable, relevant, transparent, efficient and uniform outcome measurement in both home care and residential care settings.

There are numerous limitations and caveats on the results of this process. While every effort was made to recruit panellists from all identified stakeholder sectors, the generalisation of results is limited by the proportionally low number of people living with dementia who volunteered for the Delphi panel. Furthermore, this consensus approach did not include the voice of government, although policy makers were apprised of the survey results and invited to provide feedback. Additionally, response rates across the process declined gradually for a multitude of reasons, which has the potential to bias results. The diverse perceptions and opinions of what is most important proved a significant challenge in reaching consensus. The STARDIT reports about this project and the ongoing involvement of the SRG in reporting and evaluating methods and findings will provide additional

data that will be useful for informing the methods of future research projects.

CONCLUSION

A modified Delphi consensus process has identified 31 outcomes for home care and residential aged care settings that are important, meaningful and relevant to dementia care stakeholders. This result was achieved by including representatives from stakeholder groups in an expert panel, including people impacted by dementia. Eliciting what is most important required the modification of Delphi methods to include trade-offs between outcomes. A core outcome set for quality of routine care provided to people living with dementia in Australian aged care, developed by those drawing on or providing these care services, remains a promising contribution to dementia care. The next phase of the COM-IC project aims to identify measurement instruments that are valid and reliable measures of the selected outcomes for inclusion in a practical core outcome set that could be used in dementia care settings to improve the quality of routine care provided to people living with dementia.

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HE001932). Participants gave informed consent to participate in the study before taking part.

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