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Optimising participation of persons with cognitive impairment in a national dementia registry: challenges and solutions

Introduction

Clinical quality registries (CQRs) are organisations which "systematically monitor the quality (appropriateness and effectiveness) of health care, within specific clinical domains, by routinely collecting, analysing and reporting health-related information" (1). They are increasingly recognised worldwide as a valuable tool to monitor and evaluate the quality of healthcare (1-3).

Maximising coverage of CQRs minimises selection bias and increases the validity and generalisability of data collected~~, and as such,~~. For this reason, the goal of CQRs ~~aim~~is to enrol the entire applicable population within a clinical domain (1-3). ~~The~~An opt-in consent model ~~that is~~ used in most research ~~studies~~ has been shown to lead to a sub-optimal coverage for CQRs (3-5). The Australian Commission on Safety and Quality in Health Care (ACSQHC) thus recommends an opt-out recruitment approach for CQRs in Australia (4).

For CQRs employing this approach, eligible participants are contacted and provided with information about the registry, data management, and opt-out methods (6). No action is required by participants if they choose to remain in the registry. If eligible participants elect to opt out, they are required to notify the registry and all or some of their data ~~is~~, may subsequently be removed.

~~The~~There is an underlying assumption in the opt-out approach ~~presumes~~ that potential participants have capacity to make an informed decision about participation (6). Accordingly, CQRs ~~often exclude or~~generally do not include an assessment of a person's decision-making abilities; nor do they have recruitment and consent processes in place for persons with ~~impaired decision-making abilities.~~impairments in this area. However, as the population ages, the number of people living with neurodegenerative diseases such as dementia increases and the likelihood of impaired decision-making abilities commensurately follows. Given the important role of CQRs in monitoring healthcare quality, especially for age-related conditions, there is a need to address the ethical challenges of including persons with cognitive impairment~~. This will~~ to ensure that data collected in CQRs are unbiased and reflect experience and outcomes of people regardless of their cognitive function.

To our knowledge, there is currently no clear guideline on how to address these ethical challenges. This paper describes the innovative recruitment framework employed by the Australian Dementia Network (ADNeT) Registry to include people with dementia and Mild Cognitive Impairment (MCI).

The ADNeT Registry

~~Framework to optimise participation in CQRs among people with cognitive impairment~~

The ADNeT Registry is a CQR for persons newly diagnosed with either dementia or MCI (7). It is being established in recognition of the high burden of dementia in Australia, significant consequences of poor care and support from relevant clinical and consumer organisations (8). This registry is currently being piloted at private and ~~pubic~~public memory clinics across Australia and is being expanded into other diagnostic settings, such as private specialist practice and primary care. Participating clinics enter a minimum data set into a secure database at the time of diagnosis. The Registry subsequently collects patient and carer experience and outcome measures, undertakes linkage with administrative datasets, oversees data analysis and reporting (7). Participating healthcare providers can access their own data at any point to better understand their clinical profile and practice.

The ADNeT Registry aims to ultimately enrol the entire population of persons newly diagnosed with either dementia or MCI, thereby systematically driving improvements in healthcare quality and patient outcomes ~~for this cohort.~~. This has been achieved by similar dementia CQRs internationally (9~~).~~), such as the Swedish Dementia Registry and the Norwegian Dementia Registry, which have been shown to improve patient outcomes and reduce healthcare costs (9). Different consent models (e.g., opt-in, opt-out) have been used in these registries, but none has articulated an explicit procedure to incorporate the assessment of decision-making abilities in their consent models.

Framework to optimise participation in CQRs among people with cognitive impairment

The ADNeT Registry has developed a dual recruitment framework based on the following three determinants (see also Figure 1):

1) Decision-making capacity
2) Person Responsible
3) Communication of diagnosis

(insert Figure 1 here)

This framework comprises of an opt-out approach and a number of waivers of consent. It was developed based on relevant guidelines and evidence (4, 5, 10-12), particularly the NHMRC's National Statement on Ethical Conduct in Human Research (NHMRC National Statement) (6). Extensive legal consultation was undertaken to ensure that this framework and its key associated documents comply with relevant

jurisdictional and federal legislation, such as the *Privacy Act 1988*, which includes the Australian Privacy Principles. Feedback on key patient-facing documents was also sought from consumers and their caregivers. Ethics approval was obtained from the Alfred Hospital Human Research Ethics Committee (Project Number: 44037).

Determinants of the recruitment framework

The first two determinants, namely, 'decision-making capacity' and 'person responsible', are commonly used in the context of informed consent for research using opt-in consent (10-12). Decision-making capacity is a task specific construct. In the setting of research participation, decision-making capacity hinges on the ability of ~~a participant~~participants to 1) understand and retain information about research participation, 2) apply this information to their own circumstances and value system and use this information to make an informed decision about whether to participate, and 3) communicate their decision (10-12). Where an ability to undertake any of these tasks is ~~impacted~~reduced by a cognitive disability, depending on the nature of the study, a 'person responsible' or proxy/substitute decision maker may be able to provide support in decision-making or consent on their behalf (10-12).

These fundamental principles also apply to the opt-out approach. However, there are practical constraints in implementing these principles in CQRs, such as the need to integrate data collection into routine clinical practice and to minimise clinician burden as much as possible (1, 4). For the ADNeT Registry, clinicians are not required to complete the entire consent process, as within weeks of their diagnosis, the Registry will mail potential participants information about the Registry and how to opt out. Clinicians are asked to assess and document a patient's ~~likely~~estimated ability to participate in this opt-out approach based on clinical history and performance on cognitive testing. It is recognised that clinicians, typically geriatricians, neurologists and old age psychiatrists~~,~~ who work in the clinical assessment of cognitive disorders, have the requisite skills to form an opinion on such abilities. Practical guidance (see Table 1) has been developed for clinicians at participating sites and early feedback from pilot sites indicates that this is workable.

If a participant is assessed as having cognitive impairment/s that ~~impact on~~affect their ability to participate in the opt-out approach, then the second determinant is whether there is a 'person responsible' ~~to whom~~who can instead receive the opt-out information ~~can instead be provided~~. This is a term chosen to have applicability across all jurisdictions in Australia and follows an order as set out in Table 2.

The third determinant is whether there is documentation that the diagnosis has been communicated to the patient ~~if they have been~~ assessed as having capacity, or otherwise to the person responsible. CQRs commonly only presume disclosure of diagnosis. However, there is evidence of variation in disclosure for dementia ~~as, despite guidelines, some clinicians might choose to withhold the diagnosis due to concerns~~

~~about psychological well-being or requests from family, in particular, among people from Culturally and Linguistically Diverse backgrounds (13).~~. Pooled analysis in a recent review on health practitioners' practices on communicating a diagnosis of dementia found that while most GPs and specialists usually or routinely tell the family the diagnosis, only 34% of GPs and 48% of specialists did so with the person with dementia (13). Additionally, euphemistic terms such as 'memory problems' are more often used when communicating the diagnosis than medical terms, particularly with people with dementia (13). The review also found that many factors influence practitioners' disclosure practices, including practitioners' own beliefs regarding dementia and confidence in diagnosis and communication, the circumstances of the patient, societal norms, and the health and care social system in which practitioners work (13). Therefore, 'communication of diagnosis' is included in the ADNeT Registry as a determinant.

The opt-out approach

Utilising this framework, the opt-out approach applies to two groups: 1) persons with sufficient decision-making abilities for the opt-out approach and who have been informed of their diagnosis, and 2) persons with impaired decision-making abilities but with an identified person responsible whom has been informed of the diagnosis. For these two groups, ~~an introductory~~ a postcard (see Supplemental document 1) is provided by clinicians, after confirmation of diagnosis, to introduce the Registry and to foreshadow the subsequent information that will be provided. This postcard, which was developed following legal consultation and input from consumers, aims to introduce the Registry whilst minimising the burden on patients, their caregivers and clinicians at the time of diagnosis.

Later, the patient or the person responsible receives information in the mail about the Registry and ~~various~~ its opt-out options. In invitation letters to persons responsible, we encourage them to involve the patient in the decision-making as much ~~far~~ as ~~it is~~ feasible to ensure that the participation decision is consistent with the patient's values and/or preferences~~, recognising that there is a significant variation in cognitive function and insight into diagnosis among people with dementia~~.

The ADNeT Registry recognises that there might be complex circumstances ~~for~~involved in opt-out requests. For example, a patient who has been identified as not having capacity to be involved in the opt-out approach may contact the Registry to request opt out. A patient, who has been identified as having capacity, may ask someone else to contact the Registry to opt out on their behalf, due to reasons such as a hearing or speech impairment~~,~~ or limited spoken English. In such circumstances, the ADNeT Registry will respect the wishes of the patient and take a conservative approach to opt them out of the Registry.

Waivers of consent

~~We recognise that there will be~~The Registry utilises waiver of consent to include patients who do not fit into the above two opt-out groups, such as persons with ~~more~~sufficient decision-making abilities for the opt-out approach but who have not been informed of their diagnosis, and persons with impaired decision-making abilities who do not have an identified person responsible or where the identified person responsible has not been communicated the diagnosis. ~~significant cognitive impairment, those who are socially isolated, or when local practices in diagnosis disclosure and documentation differ.~~ Arguably, these groups may have greater care needs and/or be at risk of poorer clinical outcomes (e.g., 14). It is ~~critical~~important that these groups are included in the ADNeT Registry, given ~~that~~ its explicit ~~job is to measure~~goal of improving quality of care. ~~Therefore, to promote inclusiveness and maximise coverage, a number of~~

These waivers of consent ~~apply~~also enable the Registry to include patients who have not been informed of their diagnosis. As noted above, there is evidence that significant numbers of health practitioners do not communicate a diagnosis of dementia to their patients (13). Therefore, including these patients' data in the Registry will provide better understanding of variations in diagnosis disclosure across practices/clinicians and factors underlying these variations.

When enrolling patients via a waiver of consent, the ADNeT Registry records their baseline demographic and clinical ~~and demographic data of these groups and the Registry~~data but will not contact these patients or their persons responsible. The Registry will minimise collection of patient identifiable information under these waivers of consent to protect privacy while enabling data linkage for tracking long-term outcomes, e.g., entry into residential aged care and survival. All waivers of consent meet the conditions outlined in the NHMRC National Statement (6).

The ADNeT Registry ~~is also collecting patient-~~recognises the importance of capturing longitudinal clinical data and longer-term patient and carer~~-reported outcome and experience measures (15) as is feasible and intends to collect clinical follow-up data where applicable.~~ outcomes. The same recruitment framework will ~~guide ongoing engagement~~be instituted at annual follow up data collections with ~~registry participants.~~participating clinical sites where feasible. This is particularly important ~~as~~considering decision-making capacity, persons responsible, or carers might change over time~~, especially for persons with dementia~~.

Additionally, there are likely to be specific areas of challenges when implementing this recruitment framework with special needs groups, such as Aboriginal and/or Torres Strait Islander people and CALD communities. We are establishing working groups, comprising representatives of community members, relevant peak bodies, clinicians and researchers, to ensure we receive guidance on working with these groups.

Conclusion

The ADNeT Registry will provide crucial data on clinical practice and outcomes for persons diagnosed with dementia and MCI in Australia. These data will help to identify variations in clinical practice and patient outcomes and expose factors underlying these variations. That, in turn, will inform continuous quality improvement initiatives.

Achieving maximal coverage is fundamental ~~for effective CQRs. To enable this,~~to the accomplishment of these objectives. .However, while the opt-out approach is employed by most Australian CQRs~~. However, the opt-out approach presents great~~, it does present challenges concerning inclusion of people with cognitive impairment ~~as a significant number may not have~~where the decision-making abilities required for the opt-out approach may be lacking. The ADNeT Registry's recruitment framework, based on three key determinants, maximises inclusiveness, respects the wishes of patients and caregivers, and provides an innovative model to ensure people with cognitive impairment are represented in health quality data.

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Table 1 Practical guidance on 'decision-making capacity'

Specific ability required to participate in Opt-Out Consent Process	How to assess in Clinical Consult	
	Elements from Patient and Informant History Tasking	**Elements from Cognitive Assessment**
Access materials received in postal mail	Is patient still collecting and opening their mail?	Praxis, Executive Function
Read, comprehend and retain information contained in a two-page Participant Explanatory Statement	What is the patient's usual ability with reading and comprehension, including reading of documents received in postal mail?	Language: Reading and Comprehension Attention and Concentration Memory: Delayed Recall
Apply information about registry participation to own circumstances and make a decision	What is the patients' current awareness of their own circumstances and values?	Executive Function including abstraction
Follow instructions on how to opt-out if so chosen	Can patient usually follow written instructions?	Language: Comprehension
Communicate a decision by phone call, email, or writing and sending on an opt-out form in postal mail	Can the patient still use a telephone to dial an unfamiliar number, or use a computer to send email, or return materials in the postal mail?	Executive function: planning and sequencing, and praxis Language: Speech or writing

Table 2 Definition and practical guidance on 'person responsible'

Definition	All states and territories have law and/or policy that guide the identification of a person who can support decision-making for an individual with impaired decision-making capacity, and different terms, such as "~~Person~~ Person responsible ~~is~~" and "substitute decision-maker", have been used to refer to this person. The term "person responsible" is used in the ADNeT Registry to harmonise the terminology across jurisdictions and is defined as an individual who is reasonably available and willing, and ~~is~~ able to make informed decision on the behalf of the patient where the patient does not have capacity to be involved in the opt-out recruitment process.
Practical guidance	The person responsible is defined in the following hierarchical order: 1. Medical treatment decision maker appointed by the patient 2. A guardian appointed by jurisdictional courts to make medical treatment decisions 3. The first of the following people who is in a close and continuing relationship with the patient: 1) Spouse or partner, 2) Primary carer (not professional carer), 3) An adult child, 4) A parent, 5) An adult sibling If more than one person is identified as the person responsible at the same tier within the hierarchical order, the eldest will be identified as the person responsible.