Research Plan

Title: Assessment of **DE**pression for **QUAl**ty **C**ar**E S**tudy **(ADEQUACIES)**

(i) Aims of the project

1) to examine the clinical utility of RACF staff completed CSDD assessments, compared with 30-item Geriatric Depression Scale (GDS) (either self-completed or RACF staff assisted), against clinical diagnosis of depression made by a specialist psychogeriatic clinician;
2) to identify patterns of non-completion of the Cornell Scale for Depression in Dementia (CSDD) collected in residential aged care facilities (RACFs); and
3) to develop a suite of recommended best practices for assessing depression in RACFs.

(ii) Background and Significance

Depression, with or without dementia superimposed, is recognised as the most common psychiatric disorder in the elderly, leading to poor quality of life, limited activities of daily living, suicide risk and an increased risk of medical comorbidity (1-3). Estimates of the prevalence vary depending on the diagnostic tools used, different classifications of depression, locations of populations (community dwelling or institutional populations) and methodologies related to design, sampling and treatment of co-morbid conditions. What is consistent is the high incidence and prevalence of depression in residential aged care facilities (RACFs): ranging from 6 to 24% for major depression; and 25-40% for depressive symptoms or minor depression (4-7), in particular among the 30-53% of RACF residents with dementia (8-10). According to the Australian Health and Welfare (AIHW) (11) in 2008-9 35% of RACF residents (approximately half with dementia) experienced moderate to major interference to their daily activities and functions due to depressive symptoms. Anecdotal evidence from RACF staff, our clinical observations and earlier research evidence (12) suggest the rates are likely to be much higher than reported in the literature. Nevertheless, a conservative estimate of data obtained from the ACFI database (11) suggests that 56,000 of the total 160,000 residential aged care recipients require treatment for depression. It is likely these numbers could triple by 2050 given the rate of growth of older Australians.

Studies continue to report the problems associated with under-detection, under-diagnosis and under-treatment of late-life depression, in particular in people with dementia (6, 7, 13, 14). We believe a fundamental issue for these stems from an inadequate assessment of late-life depression, particularly in RACF populations, where limited workforce capabilities and capacity lead to RACF staff poor awareness of the importance of early recognition and impede timely and appropriate assessment and management of depression.

Since its introduction in late 1980s, the Cornell Scale for Depression in Dementia (CSDD) (15, 16) has been widely accepted and utilised as a measure of depression for people with dementia. It has good reliability and validity, including high sensitivity and specificity (17-19). The CSDD has been recommended as the best measure of depression for people with dementia or cognitive impairment in the recent Australian dementia outcome measurement suite project (18) as well as internationally (20). The Australian Government adopted the CSDD as part of the mandatory Aged Care Funding Instrument (ACFI), which was introduced in 2008 as the means of allocating Australian Government subsidy to residential aged care providers. The CSDD is part of the mandatory Aged Care Funding Instrument (ACFI). Recently, the Geriatric Depression Scale (GDS)-15 has been suggested for screening of depression in older persons with no-cognitive impairment as part of the routine Aged Care Assessment Team (ACAT) assessment. However, the use of the CSDD has been noted as “a complex instrument that requires specific training in its administration” (21) (p.35).

The majority of CSDD reliability and validity test studies are based on CSDD ratings by specialist mental health clinicians or specifically trained researchers. It is not known how reliably the CSDD is administered by staff from RACFs, since there is no standardised process in place to assess their knowledge and skill base prior to administering the CSDD, a condition required by the instrument developers. A recent study conducted in the United States reports that the CSDD modified for use by long-term care residential care staff failed to detect depression (22), a finding which confirms our hypothesis that Australian RACF staff are not sufficiently armed with the necessary skills to undertake the CSDD assessment for residents with dementia.

This proposed study builds on our pilot study that investigated the construct validity of the ACFI-BEH (Behaviour domain of ACFI consisting of physical and verbal behaviours, wandering and depression) in comparison to other validated BPSD measures for such as the Cohen Mansfield Agitation Inventory (CMAI), the Revised Algase Wandering Scale (RAWS), and the Cornell Scale for Depression in Dementia (CSDD). The findings (n=55 from five RACFs) showed that in contrast to the results of the measures for verbal behaviours and wandering, there was no correlation between CSDD ratings obtained by the trained research nurse and the ACFI depression domain scores or CSDD ratings obtained by staff from the RACFs. Field notes and observations during the study suggest the problems with the implementation of CSDD by the RACF staff (and the trained research nurse) are associated with the lengthy time required to implement the tool and the difficulty of answering some items for residents with dementia. These items were CSDD 16-19 measuring Suicidal ideation, Self-deprecation, Pessimism and Mood-congruent delusions. The frequency of non-completion for these four items (i.e. unable to rate) ranged from 41.5% to 43.5% when implemented by the trained research nurse and 50-54.3% by RACF staff.

The same issues, albeit less frequently, were identified in Snowdon's study where 14% of participating residents did not have complete CSDD ratings due to their severe cognitive impairment and inability to communicate in a meaningful manner (6, 23). Snowdon's study (n=162) found "items 16–19 were often not rated, even if other items were, because ideational disturbance was too difficult to rate if a subject could not converse intelligibly or convey meaning" (23) (p.34). It is not surprising, therefore, that 20 of 98 submissions made to the first national review of the ACFI raised specific concerns about the use of the CSDD, most of which related to its complexity and time consuming nature, as well as its unpopularity among GPs. The ACFI review report (24) acknowledges these issues and indicates the need for more flexibility in the instrument choice for behavioural disturbance, including depression, such as use of the GDS (24).

Given the issues identified with screening and assessment of depression in RACFs, it is important to identify the best depression instrument and assessment process, since depression identification is an essential factor in determining adequate funding levels for individual residents and in ensuring they receive quality care. The proposed study will provide new insights as to how assessment of depression can best occur in RACFs.

(iii) Research Strategy

This study entails three phases: 1) examination of existing databases containing CSDD data collected by trained research staff to identify patterns of responses and non-responses of the 19 CSDD items; 2) examination of the clinical utility of the CSDD as administered by RACF staff as part of the ACFI assessment suite, compared with the 30-item GDS, against expert clinician's diagnosis of depression; and 3) development of a suite of recommended best-practices depression assessments for RACFs.

Phase I

Pooled data from the following four recent studies conducted by different investigators of the study team will be analysed. These data include:

- ACFI instructed DEmentia Education and Learning Trial Initiative (ACFIiDELITI) (n=55) (*Jeon, Y-H, Low, L-F, Chenoweth, L, O'Connor, D* et al.)
- The Sydney Multisite Intervention of LaughterBoss and ElderClowns (SMILE) (n=406) (*Low L-F, Brodaty H, Chenoweth L* et al.)
- Specialist mental health consultation for depression in Australian aged care residents with dementia: A cluster randomized trial (n=44) (McSweeney, K, *O'Connor, D* et al.)
- Depression in nursing homes study (n=51) (McSweeney, K & *O'Connor, D)*

With a total pooled sample size of 556, we will conduct an item analysis and examine descriptive statistics for individual CSDD items for the frequencies of items marked ***'a'*** (unable to score) and also look for patterns of the responses (items) that are closely linked to depressive symptoms (scores 7-10), probable major depression (scores above 10), and definite major depression (scores above 18). We hypothesise that the CSDD is difficult to complete even for well trained researchers and certain items of the CSDD may not contribute to the final depression categories. Findings from Phase I will inform Phase III when developing a set of recommendations for assessment of depression.

Phase II

We will examine the clinical utility of the CSDD conducted by RACF staff, compared with the 30 item-GDS, against a formal diagnosis of depression made by two experienced specialist old age psychiatry clinicians (one each for Sydney and Brisbane) using the relevant diagnostic guidelines (see below). Reliability of two clinicians' diagnostic measures will be established prior to data collection.

Setting: A total of 20 RACFs (10 in Sydney and 10 in Brisbane), covering the following diversity: high care/dementia specific care, mix of low and high care, and for profit and not-for-profit. They are comparable to each other in terms of: management structure, staffing, standards and size; holding three year accreditation status granted in the last 12 months by the Residential Care Accreditation Agency; being serviced by General Practitioners and other specialist health staff; and service provision (nursing care, therapy provision and recreation programs)

Subjects: 200 residents (100 each from Sydney and Brisbane) who have recently been assessed for depression using the CSDD by RACF staff, AND whose guardians/persons responsible have given written informed consent, as well as with resident's verbal assent.

Assessment: The following information/measures will be collected:

- Demographics (age and gender) and clinical information including type of dementia, and current co-morbidities, length of stay, cognitive levels (recorded in the ACFI based on the Psychogeriatric Assessment Scales-Cognitive Impairment Scale [PAS-CIS]) (24), and treatment modalities (non)pharmacological of depression where appropriate;
- Global Deterioration Rating Scale for Assessment of Primary Degenerative Dementia – measures severity of dementia (range Stage 1 to 7); higher scores reflect more severe stages of dementia (25);
- RACF staff collected Cornell Scale for Depression in Dementia (CSDD) (16) scores: 19 items measuring the following domains of depression- Mood Related Signs; Behavioural Disturbance, Physical Signs, Cyclic Functions, Ideational Disturbance (absent, mild or intermittent and severe: Scoring 0–2). Total score of 11-18 indicates a probable major depression. Scores above 18 indicate a definite major depression (18).
- RACF staff assisted completion of 30-item Geriatric Depression Scale (GDS) (26): it is a self-report screening and assessment instrument designed for depression in the elderly. It has 30, 15, 10, 4 and 1 item versions and is well-known for its ease of administration (and for the dichotomous use of Yes/No response) and good psychometric properties

when used for older people without cognitive impairment. Sensitivity and specificity when used for people with dementia are lower than the CSDD (18-20). Scores of 0-9 (out of a total possible 30) are considered *Not depressed*, 10-19 as *Mild depression* and 20-30 as *Severe depression* (18). From the 30-item GDS items we will also be able to examine the shorter versions of the GDS (15, 10, 4, 1 item).

- Experienced clinician diagnosis of depression: DSM-IV TR (27) to establish a formal diagnosis of depression in patients without dementia; and the Provisional Diagnostic Criteria for Depression in Alzheimer Disease (PDC-dAD) (28) to establish a diagnosis in dementia patients (both criteria recommended by the IPA taskforce) (20). The mini-mental state examination (MMSE) (29) will also be used for cognitive testing to assist diagnosis and to remedy shortfall of the PAS-CIS.

***Timing of the assessment*:** Within less than a week of the CSDD rating by RACF staff, the expert clinician who is blind to the CSDD scores will conduct comprehensive assessment of depression of those new residents. When and by whom the CSDD and the GDS have been conducted will be recorded.

Data analysis: All data will be entered and analysed SPSS version 18. Receiver operating characteristic (ROC) curve analysis will be used to examine the validity of full CSDD and 1, 4, 10, 15 and 30 item GDS against a gold standard clinician diagnosis of depression using DSM-IV-TR and the PDC-dAD. The area under the curve (AUC) will be calculated for each version of the tools. Sensitivity and specificity of the scales will be reported. The statistical significance between two AUCs will be calculated with the z-test. The level of cognitive impairment based on the PAS-CIS and the MMSE (i.e. no or minimal vs. mild to severe impairment) will be taken into account in the analysis. The scale with the largest AUC will be considered the best measure for distinguishing between depressed and non-depressed residents assuming that the costs of a false positive error and costs of a false negative error are equal. If two scales have similar (i.e. not significantly different) AUCs then the scale taking less time to administer will be considered the better measure. The optimal cutoff score for the best measure will be chosen as the score with the highest sum of sensitivity and specificity.

The sample size of 200 should give 80% power to detect a 35% reduction in accuracy (average of sensitivity & specificity) in the CSDD compared to published accuracy of 95% (19). The sample of 200 should give 80% power to detect a difference of 25% in accuracy between the 95% expected for the CSDD and the 70% expected for the GDS (30).

Phase III

Consultations with the Expert Reference Group (ERG) will be conducted to develop a suite of strategies/recommendations for best practice in the assessment of depression in RACFs. Membership of the ERG includes, but is not limited to, the study team, general practitioner, aged care nurse practitioner, managers and staff of the participating RACFs, representatives from the NSW Dementia Behaviour Management Advisory Service (DBMAS), aged care peak body (the Aged and Community Services Association of NSW & ACT Inc.), consumer representative (Alzheimer's Australia), psychometrics expert (DCRC-ABC biostatistician). The results from Phases I & II and the pilot study will inform the consultation process.

Study Procedures and timeframe:

- Stage 1 (03-05/2012): Establish an ERG; Convene a joint ERG and Project Management Committee meeting; Recruiting a research assistant; Ethics approval
- Stage 2 (06-09/2012): Data cleaning and analysis of the existing CSDD data (Phase I)
- Stage 3 (05/2012-03/2013): Recruit participants, conduct data collection & entry (Phase II)
- Stage 4 (03-04/2013): Data analysis and development of the suite of strategies and recommendations for the assessment of depression (Phase III)

- Stage 5 (04-06/2013): Final report for DCRC and publications and grant applications.

(iv) References

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