Background:

There are 4 overnight hospitalisations for every 10 older Australians each year [1], and a hospital stay is often a decisive turning point in an older persons' health [2]. Regardless of the reason for hospitalisation, older patients are at high risk of leaving hospital worse, not better. Geriatric syndromes--deterioration in physical performance and independence, nutritional status and mental state--predispose to poor hospital outcomes including falls, pressure injury, longer hospital stays and nursing home placement, and may take months to improve [2-4]. The cost to the health system is enormous; for example the costs of delirium are estimated to be greater than the health system costs for diabetes [5, 6].

Better hospital care can reduce these adverse impacts [2, 7-10]. Embedding several crucial practices (support of early ambulation and independence, support of oral nutrition and hydration, and individual/group activities for cognitive stimulation) can reduce delirium and functional decline and improve outcomes. Specialised acute care for elders wards are one effective model to deliver these practices [11-14], but with more than half of hospital bed days occupied by elders such highly specialised wards offer a solution for only a few. We must expand the principles of good geriatric care to all hospital wards caring for elders [15].

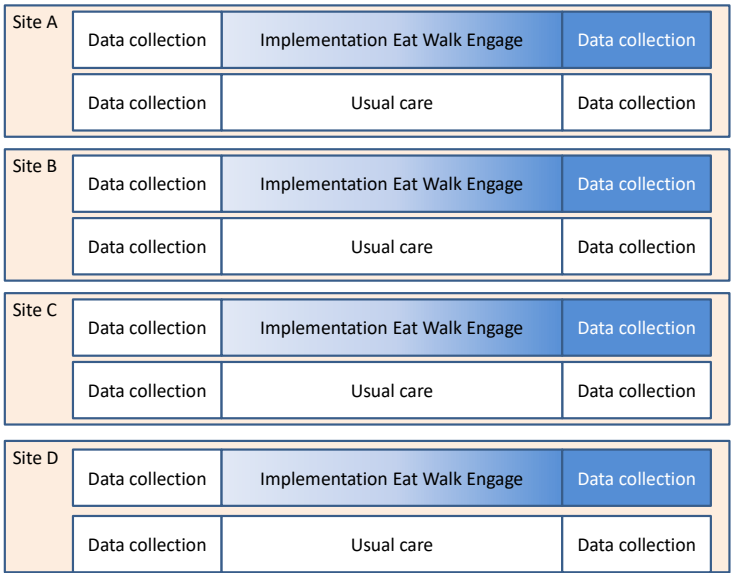
There has been increasing international interest in this problem, with several recently published research protocols and studies addressing poor nutrition, poor mobility and delirium in general ward populations [16-22]. Observational studies demonstrate complex patient, staff and system barriers to apparently simple practices such as mobility, nutrition and cognitive activities in acute wards [23-31]. The challenges of translating evidence into practice change in complex systems are increasingly recognised. Successful change requires a tailored approach which takes into account the evolving evidence, the local context (including culture, leadership, politics and resources), and complex individual and group dynamics and readiness to change, and which uses evidence-based tools for initiating and embedding behaviour change [32]. Few of the published studies have used an explicit implementation framework [20, 33], and most have focussed on providing protocol care to individual patients rather than considering wider systems interventions [15].

We have piloted "Eat Walk Engage" as an evidence-based system redesign model to improve care of older patients on two wards at the Royal Brisbane and Women's Hospital. We have used an enabling facilitation approach guided by the PARIHS framework (Promoting Action on Research Implementation in Health Services) [34, 35], with facilitation strategies including: engaging directly with patients to be responsive to their needs and priorities; facilitating clinicians leaders to make practice changes at ward level; involving the teams in meaningful data collection and feedback; investigating affordable solutions to workforce and environmental challenges; and aligning organisational governance, training, and data monitoring with these changes to ensure sustainability. We have demonstrated improvements in processes of care and reduction in hospital bed use in our before-after evaluations [36]. Average acute length of stay for patients aged 65 and older fell from 9 days to 6 days on the medical ward, and 8.5 days to 7.5 days on the vascular ward (unpublished data), a bed day saving valued at more than $2 million per year. The proportion of patients able to directly discharged home without a continuing "subacute" care stay increased by 15% on the medical ward, and by 20% on the vascular ward, meaning that 250 more patients each year do not require a continuing stay. We saw promising trends to reductions

in reported falls and pressure injuries on the intervention wards. Patients reported they were more likely to walk, receive help at mealtimes, and have things to keep their mind active. However, the wider application of these findings is hampered by the single institution location, the before-after study design, and limited qualitative information to understand key factors in intervention success.

CHERISH will build on these promising pilot findings, conducting multi-methods research within a randomised controlled trial design to investigate whether the approach is effective, cost-effective, transferable and scalable within our health system. This approach is consistent with the MRC Framework on Evaluation of Complex Interventions in Healthcare [37]. Our strong multidisciplinary team of researchers and clinicians will combine expertise in health system redesign, geriatric care, complex research methods and economic analysis. We have partnership support from 2 major hospital and health services and will engage with their clinical and executive leaders to adapt and refine our implementation approach. Partnering with the Queensland Government and hospital and health services will engage policy and decision makers in the research process and assist the translation of findings into policy and practice. Strong links with other major quality initiatives in aged care, notably the Hospital Elder Life Program (HELP, Professor Inouye), the NHMRC Cognitive Decline Partnership Centre (CDPC, Professor Kurrle) and the National Ageing Research Institute (NARI, Dr Blackberry) will allow sharing of resources and dissemination of findings.

Design: A cluster-randomised controlled trial, with participants randomised to usual care or the “Eat Walk Engage” implementation model based on their admission ward (cluster). Each participating hospital will nominate two potential wards, which will be randomised to intervention or control (see diagram below). Data will be collected for patients in months 1–6 (baseline) and months 19–24 (post-implementation). This allows changes in outcomes in intervention wards after the implementation to be compared to changes in control wards, controlling for system-wide changes unrelated to the intervention.



Aims and hypotheses:

CHERISH will investigate whether Eat Walk Engage is an effective, cost-effective and transferable model for implementing improved care of older inpatients.

Specifically, we hypothesise that comparing patient outcomes on the intervention wards during baseline and post-implementation periods, we will see:

- 10% greater reduction in length of hospital stay
- 10% greater increase in discharge directly home
- Significant reduction in geriatric complications of hospitalisation (delirium, functional decline, falls, incontinence, pressure injury); and
- Significantly greater participation in target activities (nutrition, ambulation, social and cognitive engagement);

compared to control ward changes during the same period

Sites and intervention:

Four hospitals (Prince Charles, Caboolture, Brighton and Nambour) will provide wards for the study, providing a mix of metropolitan, community, and regional hospitals. Eligible wards may be medical or surgical wards with at least 50% bed days occupied by patients aged over 65 (based on analysis of local administrative data). Two wards prepared to participate will be identified for each participating hospital. To optimise potential benefits of this programme, choice will be in consultation with key executive and clinical staff at the hospital, and will be informed by patient characteristics (number of older patients on each ward, current length of stay patterns for older patients, and patterns of monitored adverse events such as falls and pressure injury), as well as executive preferences, ward leadership and engagement, and avoiding cross-contamination (e.g., wards which share a large number of medical or allied health professional staff would not be ideal as a control–intervention pair). Nominated ward characteristics will be reviewed by the Chief Investigator and statistician and sorted into two groups (each with one ward from each hospital) to optimise the spread of case-mix (e.g., avoiding distributing all surgical wards to one group). These two groups will then be randomised by a computer generated random number, providing an intervention and control ward at each hospital. Randomising each pair of wards runs individually risks creating large differences between the control and intervention groups because of the small number of hospitals.

Control wards will continue with usual clinical care. Process and outcome data collection (described below) will be undertaken on both the intervention and control wards, during the first 6 months and last 6 months of the project. This information will not be provided back to control unit staff at the time, to avoid influencing control staff behaviour. However, at project completion these data will be summarised and provided to clinical and executive staff as a measure of ward performance, providing a starting point for post-project rollout of the model on control units if this is considered appropriate by the organisation. Implementation and evaluation of this post-project phase is outside the current project scope. Organisational reporting and feedback of efficiency measures (e.g., length of stay) and quality and safety measures (e.g., falls, pressure injuries) will continue through usual mechanisms.

Intervention wards will implement the "Eat Walk Engage" programme which supports development of local strategies to improve nutrition, early mobilisation, and cognitive stimulation for older inpatients. It consists of three linked components which will be tailored to each intervention site:

1. an evidence-based facilitation approach to optimise strategy uptake and sustainability;
2. a suite of tailored clinical and system strategies (including education, task reallocation and system and environmental redesign) developed through an iterative process of process measurement, solution development and testing, and performance feedback
3. use of a trained assistant work force.

Facilitation: At each site a clinically experienced implementation leader (facilitator) will be recruited, trained in enabling facilitation, and supported by the central project team, local clinical champions and executive sponsor(s). Barriers and enablers to implementation will be assessed through group and individual discussions with multidisciplinary ward staff and other key clinical and executive staff, guided by the PARIHS framework (Promoting Action on Research Implementation in Health Services) and informed by findings of baseline process measures and patient interviews [34, 35]. Brief minutes will be provided to participating staff to check accuracy of interpretation and as a record of discussions. Information from these sources will guide the enabling facilitation approach to redesign of care. In the intervention group, repeat discussions with key informants including clinical and executive champions and the local facilitators at the end of implementation will help to understand their perceptions of implementation success and reasons for success or failure.

Tailored intervention strategies: Process measures to capture the local patient experience will be undertaken at project commencement, including patient interviews, meal-time audits and behavioural mapping (described below), providing rich data on baseline performance for the team. Information available from existing hospital data collection systems (including incident reporting such as falls and pressure injuries) and relevant information collected during staff interviews will also be summarised for feedback. The local facilitator will work with a multidisciplinary team (MDT) of clinical staff on each intervention ward to review performance (in the areas of nutrition, mobility and cognitive activities), prioritise areas for improvement and develop potential solutions. Tailored education and training of ward staff will be provided by the facilitator using materials developed in the US Hospital Elder Life Program and the Victorian Government Toolkit "Best Care for Older People Everywhere", adapted as required by the central project team in collaboration with the developers. Task analysis with the MDT, informed by baseline data, will allow redesign of systems (e.g. change in medication time to avoid clash with meals), reallocation of staff time (e.g. using therapy time to supervise a group activity), advocating for simple environmental redesign (e.g. providing a walking destination with seating and reading material) and/or delegation of appropriate tasks to an assistant. Monthly MDT meetings led by the facilitator and ad hoc support will allow staff to reflect on solutions and refine or discard them, identify new barriers and develop new solutions. Brief minutes of these formal meetings, along with field notes from time spent on the ward, will be collected to assist the facilitators and MDT reflect on and adapt their interventions.The facilitator will help escalate persistent barriers to the executive sponsors if required. This action research process will be supported by periodic process measurement and feedback to the MDT tailored to the selected strategies.

Trained assistant workforce: Healthcare assistants may include allied health assistants or nursing assistants with a certificate IV qualification and appropriate clinical experience. One half-time assistant will be recruited for each intervention ward as part of the project, when optimal task delegation strategies have been identified by the MDT. Assistants will attend two weeks of training in Eat Walk Engage strategies delivered by members of the project team in collaboration with their local work-place supervisor and the local facilitator (see above). Training in delegation will be provided to assistants and staff members delegating to them, aligned with appropriate professional standards and with particular emphasis on the target areas of nutrition, mobility and cognition.

Participants:

Participants in this multi-methods research project will include:

1. All consecutive inpatients aged 65 or older discharged from intervention and control wards in the pre-implementation period (months 1–6) and the post-implementation period (months 19–24). Data will be obtained from existing administrative databases in each facility for length of stay; discharge destination (home, higher level of care, subacute care, inter-facility transfer or death); and adverse events (pressure injuries, falls) for all patients. Estimating 250-400 older discharges per ward per 6 months, we anticipate 1000-1600 patients in each of control and intervention groups for each period (pre-implementation and post-implementation).
2. Sample of consecutive consenting older inpatients admitted for 3 days or more for detailed clinical data collection of secondary outcomes (see below), sampled from each ward during the baseline and post-implementation periods. Our previous studies in medical and surgical wards suggest that this approach enrols 30–50% of older patients; we will aim to recruit 100 participants per ward per study period (i.e. 400 for each of control and intervention groups for each period, or 1600 participants).
3. Sample of consenting older inpatients admitted for 3 days or more for brief structured interview (estimated 10 per ward per period, or total 200 interviews) exploring patient experience of key domains (mobility, nutrition, cognitive activities) including barriers and enablers
4. Staff participants, including implementation team, multidisciplinary team and executive staff supporting the project . Discussions with staff based on the themes of the PARIHS framework are key to understanding context, engaging staff and adapting interventions as part of an “action research” framework, and forms and integral part of the “Eat Walk Engage” implementation programme [36]. Information will be captured in field notes and meeting minutes.

Measures:

Primary outcomes will be length of stay and direct discharge to home/usual care, collected routinely within the hospital administrative dataset and available for all patients aged 65 and older discharged from the study wards during the study periods.

Secondary outcomes will be geriatric complications (including functional decline, delirium, falls, pressure injury and incontinence) and clinical outcomes obtained by clinical assessment and structured chart review in a consecutive sample of consenting participants on each ward. Participants will be patients aged 65 and older with a length of stay on the study ward of 3 days or more who are willing and able to provide consent (or have a suitable proxy able to provide consent to participation).

- Functional decline will be defined as any increase in the number of basic activities of daily living for which the patient requires human assistance [38]. Using the comparator of pre-morbid baseline (2 weeks prior to admission), functional decline will be calculated at day 5, discharge and 30 days after discharge (telephone) and will be obtained by patient report supplemented if necessary by proxy (relative or nurse) report.
- Delirium will be identified at the first visit by cognitive testing using brief cognitive screening and the Confusion Assessment Method (3DCAM), undertaken by a trained clinical research officer. New onset of delirium will be identified using a combination of clinical re-assessment twice per week plus use of the chart-based Confusion Assessment Method applied to clinical notes (medical record and nursing care plans) at the end of the episode of care [39].
- Falls and pressure injury will be identified from nursing and medical records cross-checked with organisational adverse event reporting systems.
- Incontinence will be identified from medical records and nursing care plans, with pre-existing incontinence identified from patient report as part of the baseline functional assessment.

Clinical outcomes will include hospital utilisation including length of acute ward stay, any subsequent rehabilitation or transfer length of stay until true discharge from hospital; and any readmitted hospital stay within 6 months of the index admission; and discharge destination from total hospital stay (home or residential care).

Descriptive patient characteristics extracted from the record will include age, sex, usual residence, primary diagnosis, comorbidities, and hospitalisation in the previous 6 months. This will be supplemented by standardised screening of admission functional status (need for assistance in activities of daily living), cognition (Abbreviated Mental Test) and nutritional status (Malnutrition Screening Tool) by the research officer at the time of patient consent, within 2 days of admission. Frailty [40] will be defined in two ways: a brief screen defined as presence of one or more of functional, cognitive and nutritional impairment on admission (identifying patients likely to benefit from Eat Walk Engage interventions); and a comprehensive frailty index based on Rockwood's approach and validated in inpatients [41, 42]. Patient descriptive data will be used to ensure the comparability of the intervention and control groups and of the two data collection points. Summary statistics will be tabulated to compare between the groups.

Cost-effectiveness will be from the perspective of the health care system and changes to costs will consider implementation costs (project, clinical and management staff time,

consumables and overheads) and cost savings from shorter stays, fewer complications and other savings. Health benefits will be assessed using a preference based utility score (EQ5D) administered at discharge (face-to-face) and 30 days (telephone) after discharge in consenting participants in both groups, enabling estimation of quality adjusted life years gained. The questionnaire will be administered by a research assistant blind to intervention status.

Process measures will provide baseline data and identify the impact of the intervention on processes of care.

- Patient interviews will be conducted with 10 consenting participants per ward using a brief (< 10 minutes) semi-structured interview tool addressing the experience of activities related to nutrition, mobility and cognition on the day of interview; perceived importance of participation; and barriers and enablers to greater participation. Interviews will be audio-recorded in de-identified form as well as on paper to capture qualitative comments.
- Documentation review will include identification and audit of nursing risk assessment and care planning documentation related to nutrition, mobility and cognition and will be identified through medical record extraction in consenting patients.
- Meal-time audits include structured observation of the mealtime environment for each older patient on the study ward for 6 meals per ward. Observations include ward level data (staff numbers at meal time, concurrent clinical activities, meal delivery and pick up times) as well as individual patient level data (tray table set-up, patient set-up, timely patient assistance, and type of meal provided). Data collection uses a structured data collection form, and sequential patient observation before and following meal delivery.
- Behavioural mapping [43]. This is a method of systematic sampling of patient activities across 4 domains [location (bedroom, bathroom, hall, off ward), physical position (in bed, sitting, standing, walking), activity (resting, cares, self-care, eating, reading, TV, games, exercising) and company (alone, with staff, with visitors). Observations are undertaken using a consistent room sequence and at fixed time intervals, with each patient observed for a 2 minute interval several times per hour for a 4 hour interval. The average percentage of time spent in each level of each domain is calculated. Physical activity observations correlate with direct activity measurement using accelerometry. The method measures a variety of activities relevant to the aims of this project, and patterns of staff interaction with older patients.
- Assistant interventions. Records of all health care assistant interventions documented in the medical and nursing records will be extracted using chart review. This will help to describe the reach and scope of the assistant workforce intervention.

While blinding of staff and participants is not possible, data will be collected by a clinically trained research officer who is not involved in developing or delivering interventions, or in design or analysis of the study. Project officers will be trained and supervised by the project management team. Data will be entered and analysed by the project management team, and de-identified results of process measures provided to the sites to support implementation strategies.

Analysis:

Outcomes will be measured and analysed at a patient level, allowing for clustering by ward. Patient, ward and group characteristics will be described using summary statistics. Change in average length of stay will be compared between the intervention and control group using time-to-event analysis. Competing outcomes will be included to explore the impact on acute length of stay and discharge destination from acute stay (death/home/subacute or residential care) [44]. Participants who are still in-hospital at the end of study will be censored. The primary outcomes will be presented as: i) the average difference in length of stay, ii) the percentage change in discharge home. Outcomes will be presented as means or proportions and 95% confidence intervals. Plots of the cumulative risks of discharge by length of hospital stay will be compared between groups to examine the differences between groups in detail and to show whether the intervention effect varies by time in hospital.

The estimated sample size will provide 90% power to detect a difference of 10% in acute length of stay and discharge home. Proportions of participants developing secondary outcomes (e.g., geriatric syndromes) will be compared between groups using chi-squared testing. Modelling approaches (such as multiple logistic regression) will be used if needed to adjust for intergroup baseline differences, however we anticipate that the randomised design will protect against any confounding. Planned subgroup analysis of outcomes will be undertaken to identify effect at different sites and in frail versus non-frail participants.

Processes of change from staff and patient perspective as well as direct measurement of observable care processes will provide information regarding intervention fidelity, barriers and enablers. Pre-implementation interviews with patients will be analysed using a mixed methods approach, with descriptive statistics for dichotomous or scale response questions, and thematic analysis of open-ended interview questions. Interview themes supported by examples will be provided in feedback to staff supplementing the objective process measures, as illustrative individual narratives can provide powerful motivation for change. Post-implementation interviews will help to identify barriers and success factors for implementation. Process measures (e.g. proportion of patient time spent standing or walking) will be measured and reported at a ward level.

Cost-effectiveness will be assessed by modelling the change to total costs and total health benefits, with uncertainties included. The cost per quality adjusted life year gained from wider adoption of the programme will also be estimated.

A participant flow diagram will be used to show: the number of participants initially assigned to each group, the number consenting to additional data collection and the losses to follow-up for secondary outcomes. Difference in consent and losses will be compared between groups using cross-tabulations and chi-squared tests.

All analysis will use an intention-to-treat approach, i.e.patients will be analysed as being part of the intervention group even if they did not receive specific interventions.

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