**FULL PROJECT TITLE**

Testing the Deterioration Early Warning System (DEWS) for residential aged care. A feasibility study.

**SHORT TITLE**

DEWS testing

**RESEARCH REFERENCE NUMBERS**

|  |  |
| --- | --- |
| Ethics project ID | 26938 |

**DEFINITIONS**

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| --- | --- |
| Age-related residential care (ARC) | Generic term for providers of long-term care services under the Age-related Residential Aged Care Services Contracts |
| Deterioration Early Warning System (DEWS) | A system to support healthcare staff to recognise and respond to deterioration. Includes the DEWS tools alongside communication, education, measurement to see how the system is working and effective governance structures. Includes a set of tools to support the healthcare staff team to recognise and respond to acute deterioration. Includes associated user guideline and education slides. |
| DEWS tools | Quick-DEWS for health care assistants  DEWS-RN for Registered Nurses  SBARR-DEWS handover tools |
| DEWS eco-system | Includes the DEWS and the quality improvement package provided for the implementation and feasibility study testing |
| Quality improvement package | All non-clinical measures and processes supporting the implementation of the DEWS tools |
| Project Leadership Team (investigators) | Research investigators: team leading the feasibility study overall |
| ARC project team (participants) | Research participants: A team of people based in each ARC facility with responsibility for leading the implementation of the DEWS eco-system (DEWS tools and quality improvement package required to implement DEWS) |
| Healthcare staff (participants) | Generic term that includes all clinical staff working in ARC includes health care assistants, registered and enrolled nurses and primary care provider |

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# A: KEY STUDY CONTACTS

|  |  |
| --- | --- |
| Project Leadership team (INVESTIGATORS) | |
| Project role | Details |
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|  |  |
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| Project Sponsor (FUNDER) | |
| Project role | Details |
| Project sponsorship Tāhū Hauora Health | Nikki Grae, Senior Manager, Quality Systems. Hauora Health Quality & Safety Commission 650 Great South Road, Ellerslie, Auckland [Nikki.Grae@hqsc.govt.nz](mailto:Nikki.Grae@hqsc.govt.nz) |

**ROLES AND RESPONSIBILITIES**

| Individual | Role summary |
| --- | --- |
| Honorary Associate Professor Michal Boyd | Research methodology review and credibility.  Sign-off and submit ethics application.  Review data analysis and publications.  Copyright ownership DEWS – approval of changes to DEWS tools |
| Julie Daltrey | Clinical leadership for tools and application in the field  Draft ethics application and research protocol.  Work up analysis, writing and approval of publications.  Copyright ownership DEWS – approval of changes to DEWS tools |
| Katrina Hutchins | Quality improvement (QI) expertise  Education training and support of ARC facilities in QI  Lead QI measurement and supporting documents |
| Mahasweta Mistry and  Rachel Spooner | Support project and manage timelines |
| Ying Li and Alexis Wevers | Support with data analysis and reports |

# B: STUDY SETTING

This study is based in aged-related residential care (ARC) facilities across New Zealand. The ARC sector is a collection of privately owned services with different delivery models (for profit, not for profit approaches, corporate group, religious and welfare & individual ownership) that do not fit under the Te Whatu Ora localities (previously DHB) system.

This study is a collaboration between University of Auckland researchers and Te Tāhū Hauora Health Quality & Safety (Te Tāhū Hauora) the body charged with quality improvement leadership in Aotearoa New Zealand

# C: STUDY DESCRIPTION

# This is a type 2 hybrid feasibility testing study [(Pearson et al., 2020)](https://sciwheel.com/work/citation?ids=10020270&pre=&suf=&sa=0&dbf=0). It will test the impact of the Deterioration Early Warning System (DEWS) on staff processes related to the recognition of and response to acute deterioration. Recognising and responding to acute deterioration is a core clinical practice expectation, one that is already being met in a multitude of ways. DEWS provides standardised guidance to support staff to meet this core exception. As a hybrid study it will test

# The ability of DEWS: a recently developed standardised set of clinical tools to help ARC healthcare staff to recognise and respond to acute deterioration.

# The effectiveness of the quality improvement package to support the implementation of the DEWS.

# It is anticipated that the DEWS will improve recognition and response processes. At the worst it will be non-inferior to current clinical processes. The DEWS is a “track and trigger” tool. It tracks resident health through on-going observation by healthcare assistants (HCA) during routine clinical care. It triggers an assessment by the registered nurse (RN) when change is noted by the HCA. It supports RN clinical communication with the primary care provider or other responding service.

# This is not considered a resident (health consumer intervention) because tracking of resident health by HCA will continue to be observational and the resident will not be aware of any changes. Should an issue be identified a RN assessment and referral will be actioned. The resident experience of this will be ‘business as usual’.

# The change we are testing is the feasibility of using a standardised process (DEWS) to support healthcare staff with this core clinical practice expectation and the quality improvement activities need to implement DEWS in the ARC environment.

# Aims

* To test the feasibility of implementing DEWS tools in ARC
* To determine whether the DEWS tools are effective in supporting ARC healthcare teams to recognise and respond to acute deterioration.
* To determine the efficacy of the quality improve package to support the implementation of DEWS tools

**Objectives**

* To determine whether
  + the use of DEWS supports the timely recognition of acute deterioration.
  + the use of DEWS supports a timely response to acute deterioration.
  + the DEWS tools impact on nurse confidence in management of acute deterioration
  + implementation of DEWS is warranted and can be recommended as a best practice activity.
* To understand
  + the experience of staff using the DEWS.
  + the impact of DEWS on clinical communication
  + the cost and benefit of DEWS implementation in ARC
  + key barriers and enablers to DEWS implementation

# Background

Approximately 34,600 people live in ARC in Aotearoa New Zealand. They are NZs oldest and most frail citizens. On average people move into care when they are 85 years old and up to 80% are estimated to be affected by frailty [(Liau et al., 2021)](https://sciwheel.com/work/citation?ids=12495798&pre=&suf=&sa=0&dbf=0). Frailty is a clinical syndrome of decreased physiological reserve resulting from an accumulation of deficits in multiple systems [(Morley et al., 2013)](https://sciwheel.com/work/citation?ids=3851230&pre=&suf=&sa=0&dbf=0). People living with frailty (PLWF) are highly vulnerable, even minor stressors can trigger catastrophic health deterioration [(Kojima, 2015)](https://sciwheel.com/work/citation?ids=7497852&pre=&suf=&sa=0&dbf=0). In the event of an acute illness PLWF are more likely to die than their non-frail counterparts (Clegg et al 2013; Kojima et al 2018; Stow et al 2018).

The timely recognition of acute deterioration in PLWF is critical to getting them the right treatment, in the right place, at the right time (Daltrey et al 2022; Laging et al 2018). This task is difficult because physiological changes associated with frailty mean acute illness often presents with unusual or non-specific symptoms [(Chambers et al., 2022; Hodge et al., 2023; Simon et al., 2022)](https://sciwheel.com/work/citation?ids=15363426,13829773,13398021&pre=&pre=&pre=&suf=&suf=&suf=&sa=0,0,0&dbf=0&dbf=0&dbf=0). Delays in the recognition of acute deterioration in ARC have been identified as key components of adverse events in NZ and overseas [(Mowat et al., 2022; Wall, 2016;](https://sciwheel.com/work/citation?ids=13754196,9622970&pre=&pre=&suf=&suf=&sa=0,0&dbf=0&dbf=0) [Andersson et al., 2018)](https://sciwheel.com/work/citation?ids=3826845&pre=&suf=&sa=0&dbf=0). It is the presentation of non-specific symptoms in the event of acute deterioration that is thought to contribute to health professionals not fully recognising patient acuity [(Bingisser & Nickel, 2019; Karakoumis et al., 2015; Limpawattana et al., 2016; Samaras et al., 2010; Wachelder et al., 2017)](https://sciwheel.com/work/citation?ids=14446700,5449789,7000685,1788056,12305495&pre=&pre=&pre=&pre=&pre=&suf=&suf=&suf=&suf=&suf=&sa=0,0,0,0,0&dbf=0&dbf=0&dbf=0&dbf=0&dbf=0).

There are currently no validated systems or tools to support the healthcare team working in ARC to recognise and respond to the acute deterioration of residents [(Chambers et al., 2022; Daltrey et al., 2022; Hodge et al., 2021)](https://sciwheel.com/work/citation?ids=11317420,13451614,13829773&pre=&pre=&pre=&suf=&suf=&suf=&sa=0,0,0&dbf=0&dbf=0&dbf=0). The Deterioration Early Warning System (DEWS) is an evidence based set of tools developed by Daltrey and Boyd to fill that gap.

**Development of DEWS**

To ensure the DEWS was based on the best available evidence and responsive to ARC needs the tool was developed using a three phase mixed methods research design. A cross sectional cohort study of routinely collected health data (interRAI) was used to establish a statistical correlation between clinical indicators of acute deterioration and mortality and morbidity. Interviews with ARC staff, residents/kaumātua, family/whānau and visiting health professionals established signs and symptoms used in practice to identify acute deterioration. This was followed with a co-design process and iterative testing to finalise the DEWS tools. The final DEWS includes three tools (table 1) and a supporting guideline.

|  |  |  |
| --- | --- | --- |
| Table 1 | | |
| Tool | User | Purpose |
| **Quick DEWS** | Healthcare Assistant | To identify key changes that may indicate acute deterioration  To trigger a referral to RN for further assessment |
| **DEWS RN assessment** | Registered Nurse (RN) | To guide a structured clinical assessment of person suspected of being acute unwell  To support RNs to initiate some standard nursing treatments.  To provide an escalation pathway in response to clinical risk / urgency. |
| **SBARR DEWS communication tool** | RN | To support clinical reasoning  To provide structured clinical communication between RN and responding clinician |

**Aotearoa New Zealand Context: contribution to new knowledge**

Use of early warning tools to recognise and respond to acute patient deterioration in hospitals has become an international best practice standard. Te Tāhū Hauora has successfully introduced early warning systems (EWS) in NZ hospitals for adults, maternity patients and paediatric populations. These tools are based on the measurement and comparison of an individual’s vital signs recorded several times a day. For people living in ARC the constant monitoring of vital signs is not warranted for two key reasons

1. People living in ARC are generally well and in receipt of long term care for age-related disability. They may experience acute episodes while living in ARC but this is not the reason for moving into care. People living in ARC are living at home (albeit a group home). Generally well people, living at home, do not monitor their vital signs several times a day, every day, it is clinically unnecessary and potentially harmful (impact on a person’s quality of life & trauma from blood pressure cuffs). From a service delivery perspective frequent vital sign measurement could compromise the contractually required ‘homelike’ environment and be an unreasonable drain on staffing resource.
2. Vital sign EWS have been trialled in UK care homes (facilities staffed by unregulated healthcare workers) they have not proven to be effective in detecting acute deterioration (Barker et al., 2019; Russell et al., 2020; Stocker et al., 2021). Healthcare workers do report an associated positive effect on clinical communication and confidence associated when using an EWS (Hodgson et al., 2022; Russell et al., 2020). There is no research considering resident acceptability.

The DEWS tools were co-designed with ARC. They are specifically designed to support ARC healthcare staff (regulated and unregulated) to recognise and respond to the unique pattern of clinical indicators most commonly seen in the event of acute deterioration in this population [(Chambers et al., 2022; Daltrey et al., 2022)](https://sciwheel.com/work/citation?ids=13451614,13829773&pre=&pre=&suf=&suf=&sa=0,0&dbf=0&dbf=0). It is anticipated that the DEWS tools will standardise the detection of acute deterioration in people living in care and support ARC staff in their work. However only small scale testing of DEWS tools was possible during the co-design research phase. This study will more thoroughly test the DEWS tools and the supporting quality improvement implementation package and will provide clearer evidence of whether wide scale implementation of the DEWS tools in ARC is feasible and warranted.

**D. STUDY METHOD**

# This type 2 hybrid [(Pearson et al., 2020)](https://sciwheel.com/work/citation?ids=10020270&pre=&suf=&sa=0&dbf=0) feasibility testing study will take a mixed methods approach to test

# The ability of DEWS to help ARC staff to recognise and respond to acute deterioration (clinical effectiveness).

# The effectiveness of the quality improvement package to support DEWS implementation

**Study design and framework**

DEWS clinical effectiveness

* The Reach, Effectiveness, Adoption, Implementation and Maintenance (RE-AIM) framework has been used to help plan this study. The RE-AIM framework has been used for over two decades to support the implementation of evidence based health interventions. It is an adaptable framework, that has been used in multiple countries and cultures. It can be used for planning, conducting, evaluation and reporting on interventions. Used iteratively during implementation it can help teams respond to road blocks or manage unanticipated issues so provides the flexibility needed when testing an new system. It also allows researchers to “plug-in” validated evaluation tools / theories to meet the needs of the project [(Glasgow et al., 2019)](https://sciwheel.com/work/citation?ids=7026403&pre=&suf=&sa=0&dbf=0).

Quality improvement (QI) package

* This study will adapt the QI package used in Te Tāhū Hauora’s successful implementation of hospital early warning systems. Adaptation will be necessary to accommodate the differences between delivering a programme in a Te Whatau Ora and the ARC sector.

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| RE-AIM: Clinical effectiveness | | |
| Domain | What do we want to know | How will we know it? |
| Reach | Have we reached target audience | * Recruit a representative sample of ARC providers |
| Effectiveness  Test DEWS tools are effective in | Do DEWS tools support ARC staff to recognise and respond to acute deterioration | * ARC teams to prospectively provide de-identified clinical case narrative of DEWS escalations. * End of project invitational semi-structured interview * Prospective audit of use of DEWS tools. |
| Does DEWS support RN decision making and empowerment | * End of project invitational semi-structured interview/focus group (voluntary) |
| Does DEWS support effective clinical communication | * ARC teams prospectively review completed SBARR-DEWS forms and share deidentified information only * End of project invitational semi-structured interview/focus group (voluntary) |
| How do DEWS facilities compare to those using current practice for recognising and responding to acute deterioration | * Ask ARC providers with the capability to benchmark to compare outcomes. * Compare rates of emergency department presentation, hospitalisation and death national deidentified data (pre and post feasibility study) |
| Did DEWS make a difference | * Pre and post facility numbers of afterhours primary care consultations, primary care ‘acutes’ and ambulance attendance numbers |
| Adoption | Do draft guidelines DEWS meet ARC needs? | * Prospective collection of issues that need to be address in DEWS guideline (2 weekly meetings with ARC teams – meeting minutes) * Field notes |
| Does DEWS training meet ARC needs | * Feedback and any ‘work arounds’ or adaptations that ARC use |
| What organisational culture norms exist that can support DEWS tool use | * Review ARC processes / policy / practices and norms that will be impacted by DEWS * Field notes |
| What organisational culture norms exist that may be a barrier to DEWS tool use e.g. models of care or digital systems | * Collect base line characteristics of facility models at recruitment for evaluation later * End of project invitational semi-structured interview * Field notes |
| Implementation process | How well are DEWS tools completed | * ARC teams complete weekly audit using standardised tools provided, collects de-identified data only |
| Did having a QI approach support teams to implementation DEWS tools? | * End of project invitational semi-structured interview * Prospective two weekly meetings (meeting minutes) to problem solve and address |
| What does DEWS implementation cost ARC? | * ARC assess using pragmatic cost template supplied [(Jones Rhodes et al., 2018)](https://sciwheel.com/work/citation?ids=13256726&pre=&suf=&sa=0&dbf=0) |
| How does the implementation process progress | * Document (minutes) of two weekly support meetings during planning, testing project phases |
| Maintenance | Are DEWS tools being used after implementation period | * Follow up phone survey ≥ 6 months. Collects non-identifiable data |
| Were there any unintended consequences of feasibility study implementation | * Documented (minutes) at support meetings * End of project invitational semi-structured interview |
| Future developments needed? | * End of project invitational semi-structured interview * Revisions to DEWS tools as indicated from feasibility study |
| Is the large scale implementation of DEWS tools across the ARC is warranted and practical / reasonable | * End of project invitational semi-structured interview * Project evaluation report project leadership team |

**E. DEWS FEASIBLITY STUDY STRUCTURE**

The DEWS feasibility study sits in a project structure (figure 1).

**Feasibility Study Production Team**

* The ARC executive provides the project leadership team with the requisite authority to access ARC facilities. As private organisations the executive will also authorise human resources required for the project.
* The project leadership team (feasibility trial investigators) are responsible for the delivery of this project
* The ARC project team (participants) includes the ARC staff running the facility level project activities and the healthcare staff using the DEWS tools. We aim to have three to five ARC facilities enrolled in this study

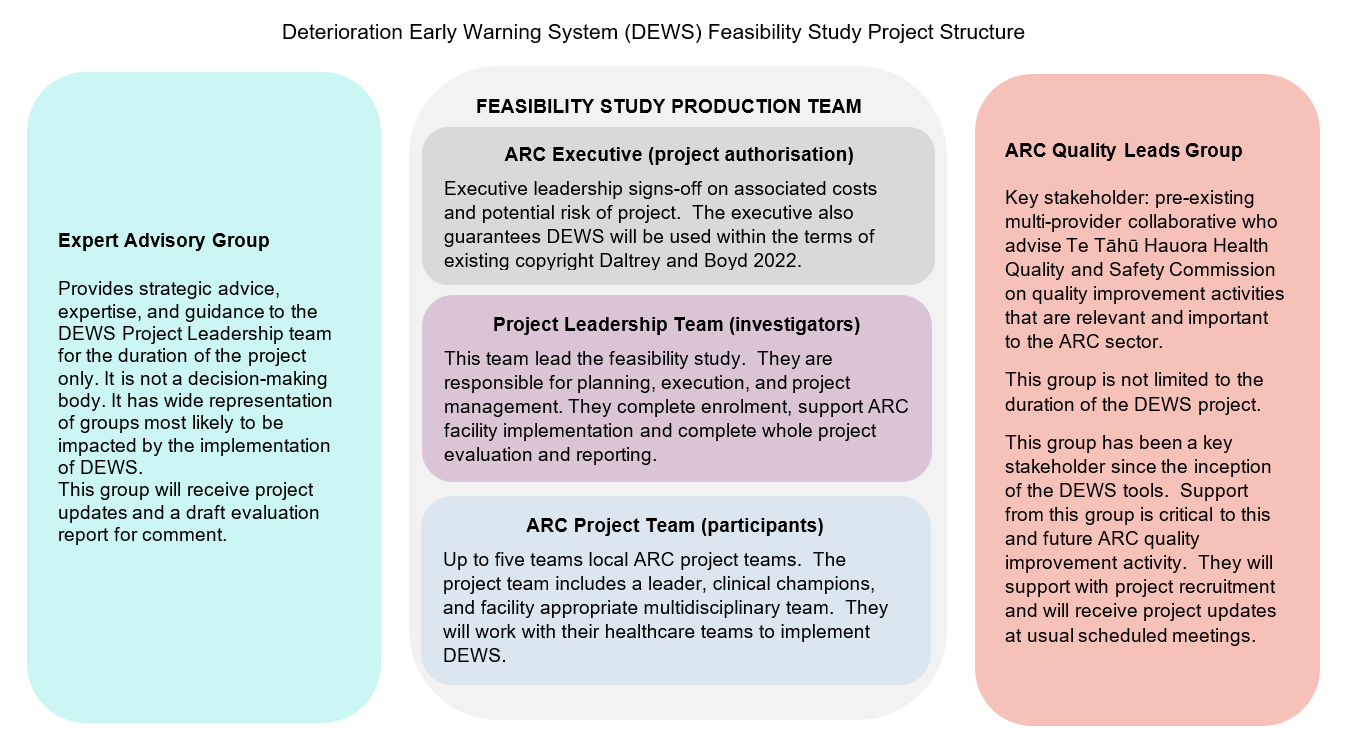
**Expert Advisory Group (EAG)**

* A supporting Expert Advisory Group (EAG) will be established to provide strategic advice to project leadership team. There will be periodic consultation with the EAG (1-2 monthly as project progress requires) to ensure the leadership team have explored and understood the potential impact of DEWS on groups directly and not directly involved in the study and to seek advice on evolving issues. This group is required as we are testing the feasibility of the further implementation of DEWS in the ARC sector.

**ARC Quality Leads Group**

* Key stakeholder: pre-existing multi-provider collaborative who advise Te Tāhū Hauora on quality improvement activities that are relevant and important to the ARC sector. This group has been an essential part of the DEWS tools development. They will support recruitment and will share project updates with ARC sector providers they represent.

**Figure 1:**



**F. FEASIBILTY STUDY ACTIVITY OVERVIEW**

**Project activities and timeline (participants)**

ARC facilities enrolling into this feasibility study will be invited to implement and test the DEWS tools and quality improvement (QI) package. The ARC project teams will lead the day to day implementation of DEWS. They will be supported by the Project Leadership Team (investigators) who will provide all necessary tools and support with QI processes to implement and test DEWS. Project activities have been split into plan, prepare, test and evaluate phases.

**Figure 2: Project timeframe and activities**

A diagram of a project management system

Description automatically generated with medium confidence

**G. FEASIBILTY STUDY PHASES**

**1) PLAN** (~ 2 months December 2023 to January 2024)

**1.1 Participant activities**

* Age-related residential care (ARC) executive leadership or delegate
  + assess study requirements, authorise investigators access to ARC facilities and provide consent for facilities to participate
  + delegate ARC project team responsible for leading DEWS testing in facility
  + determine governance for ARC project team (connect with existing team / process)
* ARC project team (participants) host in-person meeting with investigators. Cultural Protocol for welcome into facility to be determined by host
  + TIME: half day visit (4 hours) ARC team will need to structure this visit. The face to face time with investigating team may be delegated to appropriate ARC team members. Aim of visit is for ARC project team to:
    - Receive project implementation plan and get overview of DEWS tools
    - Work with investigators to identify current baseline processes for recognising and responding to acute deterioration (includes policy / procedure custom and practice)
    - Pragmatically consider and begin refining data collection plan (based on what is reasonable and accessible)
    - Complete an initial exploration of practical considerations (e.g. size of QI team, timelines, staffing, communication pathways, online QI resources)
* ARC project team (participants)
  + Beginning reading and working through implementation and planning guide *“A guide to preparing and implementing the Deterioration Early Warning System | He aratohu hei whakarite pūnaha kitenga wawe i te āhua tauheke”* in preparation for in-person workshop.
    - Think about current state
    - Begin completing project charter template

**1.2 Investigator responsibilities**

* Thoroughly socialise project at ARC facilities includes supporting ARC based project team with activities they identify as important including (but not limited to)
  + Meeting key members of the ARC team includes any necessary cultural protocols (guided by ARC team)
  + Providing in-service overview of project
  + Talking to primary care provider
* Understand current processes for recognising and responding to acute deterioration through activities such as
  + Reading local policy / procedure
  + Asking about ARC team custom, practice and variation (e.g. appointment diaries, handover sheets, handover meetings)
  + Understanding communication pathways during office hours and after hours (e.g. telephone / text / virtual consult trees)
  + Understanding boundaries of primary care service
* Refine data collection plan in line with ARC facility capacity and capability, e.g. consider and discuss
  + Electronic versus paper systems
  + ARCs ability to search their systems to gather baseline
  + ARCs ability to compare feasibility study data with established benchmarking data
  + Human resources

**2) PREPARE** (~3 months February to April 2024)

**2.1 Participant activities**

* Attend “How to” workshop to receive study information, resources and preparation support
  + TIME: full day activity for two to three members of ARC project team to:
    - Receive train the trainer information about DEWS tools
    - Receive quality improvement theory and practices required for project
    - Complete first draft of escalation mapping tool
    - Explore and understand data collection activities
    - Complete on-the-spot problem solving of issue(s) identified in planning phase
    - Build peer networks
* Continue working through planning and implementation guide
  + Complete project charter template
  + Work with primary care provider to finalise escalation mapping tool
  + Introduce and socialise project with healthcare team so they can raise concerns ask questions
  + Identify clinical champions whose support for DEWS will influence the clinical team
  + Identify existing processes were DEWS reporting will support DEWS testing (e.g. clinical handover)
* Virtual meetings: ARC project team attend every two weeks with investigators and other ARC facility project teams
  + TIME 4 to 5 meetings of 1 hour via zoom for ARC project team / team representative (ARC decision whether this complete ARC project team or representative)
    - Update on progress towards testing
    - Trouble shoot and revise plans
    - Collective on-the-spot problem solving of issue(s) identified in planning phase
    - Building peer networks

**2.2 Investigator responsibilities**

* Provide “How too” workshop
  + Planning and hosting workshop, includes any necessary cultural protocols (guided by ARC team)
  + Provide resources
  + Focus on workshopping so remain responsive to ARC environment, confirm / refine data collection activities, on-the-spot problem solving of issue identified in planning phase
  + Build a peer network for participants
* Meetings
  + Chair / facilitate meetings
  + Secretariate for formal records
  + Complete field notes
  + Follow up any issues identified including EAG advise if appropriate
  + Keep activities within scope of project
  + Work with teams to resolve roadblocks

**3) TEST** (~ 5 months May to September 2024)

**3.1 Participant activities**

* Use of DEWS tools begins (spread now includes all clinical team)
  + Healthcare assistant document Quick DEWS status once per shift
  + DEWS-RN assessment occurs if Quick DEWS is triggered
  + SBARR-DEWS completed for referral to primary care / next service as required.
* Manage issues of DEWS tools use as they arise
* Collect and provide data to investigators
  + Identify any issues with data collection
  + Use data collection to identify issue with testing
* Virtual meetings: ARC project team attend every two weeks with investigators and other ARC facility project teams
  + TIME 8 to 9 meetings of 1 hour via zoom for ARC project team / team representative (ARC decision whether this complete ARC project team or representative)
  + Update on testing progress
  + Trouble shoot and revise plans / timelines
  + Collective on-the-spot problem solving of issue(s) identified
  + Narrative examples of use of tools
  + Building peer networks
* ARC project team (participants) host one planned site visit from investigators
  + TIME: half-day visit (4 hours) ARC team will need to structure this visit to get most from the Project Leadership Team. The face-to-face time with investigating team may be delegated to appropriate ARC team members. Aim of visit is to:
    - Get a formative understanding of progress
    - Provide support for ARC team (such as talk to staff or help with data collection), understand practical issues, celebrate successes and unpack challenges
* Work with Project Leadership team to schedule and organise evaluation interviews / hui for ~October 2024
  + The interview method (focus group or individual, face to face or zoom) will be determined by that which places least demand on participating facility and staff (determine by ARC).
  + Healthcare staff consent for this process will be required (ie voluntary feedback)
    - Ideally includes interview with primary care and/or other service that received referral from staff during DEWS testing

**3.2 Investigator responsibilities**

* Feasibility study progress points; online forum every two weeks with all ARC teams to document process, troubleshoot, pragmatic revision of timelines / objectives if required, review and discuss data collection.
  + Option to do this as single site only, for site specific discussion and discussion of items that ARC facilities may not feel comfortable discussion in an open forum.
* On-site visit to support, trouble shooting, maintain momentum and understand how DEWS tools have been socialised as part of formative evaluation (investigators make field notes)
  + Understand from ARC team specific support is required.
* Review data collected and submitted by ARC sites and provide feedback to ARC sites so they have a measure of their progress
* Draft October evaluation meeting schedule

**4) EVALUATE**  (~ 2 months October – November 2024) and follow up ~ 6 months)

**4.1 Participant activities**

* Gather final data
  + ARC project team provide final data includes resolving any data gaps
* Participate in evaluation interviews: ARC project team and ARC staff semi-structured interviews
  + TIME interview will take up to 1 hour. The interview method (focus group or individual, face to face or zoom) will be determined by that which places least demand on participating facility and staff (determine by ARC) aim to.
    - understand the experience of using DEWS
    - identify barrier, enablers and lessons learned
    - collect recommendations for changes to tools
* Review draft evaluation report provided by investigators includes any changes any to DEWS eco system
* Accept virtual connection with investigators at ~ 6 months (voluntary consented process)
  + TIME interview will take up to 1 hour.
  + Is facility continuing to use DEWS
  + Why is that

**4.2 Investigator responsibilities**

* Gather and analysis final data from all ARC project teams
  + Feedback and lessons learned interviews
  + Refine DEWS tools and Quality improvement implementation package as required
* Complete draft and final report
  + Understand ARC facilities interest in next steps
* Survey at 6 months re sustainability

**H. STUDY MEASUREMENT DETAILS**

It is anticipated that the following measures will be able to be collected by the ARC project team. However this is a draft measurement plan that will need to reviewed by participating ARC teams. It may need to be adapted to suit the capacity and capability of the ARC provider and project team. All data collected will be deidentified and no trace back to individuals will be possible.

**QUALITATIVE**

* **Semi structured interview ARC project teams and ARC healthcare staff**
  + Individual or focus group at participant convenience and/ or ARC capacity. Options are face to face at the ARC facility or teleconference for people unable to make the date. Completed at end of implementation.
  + Transcribed and analysed thematically
* **Meeting minutes and field notes**
  + These will be considered research data and thematic analysis for themes will be conducted includes case narratives of DEWS escalations
* **Semi structured interview ARC project teams / team representative**
  + Virtual contact to see if facility continued to use tools after feasibility study

**QUANTATIVE EVALUATION**

* **Survey of specific elements of study** 
  + Individual survey open and closed questions. Provides an anonymous way to provide feedback that participant may not feel comfortable sharing in an interview situation
* **Audit DEWS tools use** (an audit form will be provided)

**Tool use**

* Quick DEWS completion.
* RN-DEWS completion.
* SBAR DEWS completion.

**Tool elements**

* Correct calculations
* Modifications
* Adherence to escalation pathway.
* **Change in rates of**
  + Unanticipated deaths
  + Ambulance service attendance
  + Number of acute consultations by primary care
  + Costs to ARC of primary care consultations
  + Number of call to primary care providers triggered by DEWS
* **Project costs**
  + Costs associated with implementation of DEWS spread sheet tool supplied

**I. RECRUITMENT AND SAMPLE**

We aim to recruit between three and five ARC facilities. An advertisement (invitation to participate) will be distributed via the Quality Leads Group and standard Te Tāhū Hauora communication pathways. ARC providers responding to the invitation will given more detailed information (Participant Information Sheet) and asked questions to ensure they meet inclusion criteria.

**Sample**

This will be a convenience sample however aim to recruit a reasonably representative sample of ARC providers. To ensure we recruit sufficient RNs to test DEWS we will recruit facilities no smaller than 50 beds. As there are no mandated staffing ratios in ARC this facility size is an estimate based on clinical practice knowledge. In the event of over subscription the sampling criteria below will be used to get the representative ARC sample. One ARC facility will meet more than one criteria.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Size | Population | Service model | Level of care | Geography |
| Large ≥ 70 beds  Small 50 to 70 beds | ≥ 20% Māori staff\* | Corporate for profit  Not for profit  Religious and welfare  Private ownership | Hospital and/or Rest Home and/or Secure Dementia Care | Urban  Rural |

\* in 2020 the percentage of Māori working as personal care assistants was 17% (in home based support services and aged residential care combined) and 9% were registered nurses (Te Rau Ora 2022)

**Eligibility Criteria**

To be eligible ARC providers must be delivering long term aged-related residential under the Age-related residential care services contact. Healthcare staff are all competent adults aged 18 to 75 years.

**Inclusion criteria**

ARC providers who

* sign a formal access agreement at the executive level
* hold accreditation to provide ARC services
* have a bed capacity of 50 or above
* have a contracted primary care provider with at least one year experience at the facility
* agree to provide sufficient human resources to meet needs of project.
* agree to honour the intellectual property and copyright of DEWS authors (Daltrey and Boyd 2022),

**COPY RIGHT AND INTELLECTURAL PROPERTY**

Associate professor Michal Boyd and Julie Daltrey designed and developed the DEWS in a three-phase research project “Developing a Deterioration Early Warning System” funded by Ageing Well National Science Challenge, Ministry of Business, Innovation & Employment, New Zealand (project 3720418).

* The DEWS tools (Quick-DEWS, DEWS-RN, SBARR-DEWS) and supporting materials are the copyright **©** Julie Daltrey and Michal Boyd (2022) they may not be copied, distributed, or adapted, or loaded into patient management systems without authors permission (j.daltrey@auckland.ac.nz)

**Exclusion criteria**

ARC providers will be excluded if they:

* cannot provide a formal access agreement at the executive level
* do not hold accreditation for providing age-related residential care services
* do not have a reliable and usual contracted/employed primary care service that has been in place for at least one year prior to the start of the project
* cannot release staff to meet requirements of project
* have less than 50 bed total capacity
* are unwilling to agree to intellectual property and copyright protections

**J. RESPONSIVENESS TO MĀORI**

Māori consultation was undertaken throughout the development and codesign of DEWS. For the initiation of the feasibility study implementation the research team have consulted with and have the endorsement of Ahuahu Kaunuku (Te Tāhū Hauora Māori health outcomes team) and Māori leadership is included the Expert Advisory Group. If there are cultural issues that require additional consultation (over and above the EAG) the research team will refer to Ahuahu Kaunuku.

* **Site visit**

Welcome protocol will be determined by provider.

* **How-to workshop**

Welcome will reflect the wairua of the DEWS work. We will open and close with karakia and make deliberate use of whanaungatanga to ensure all those involved feel safe and a space is created to come together. We will ensure the holistic aspects of the DEWS tools are well explained ensuring that it is understood this is more than a Māori world view.

* **Zoom sessions**

Build on the above using a bi-cultural approach to best reflect the work that has gone into the development of DEWS.

# k: ETHICAL CONSIDERATIONS

* Anonymity

This is a feasibility study implementation of DEWS using QI methodology. The participants are healthcare staff who are known to each other. In addition we will be bringing together two to three staff members from each participating ARC team for education, peer support and regular support meetings. Anonymity is not possible in this group.

* Confidentiality
  + DEWS tools information: This feasibility study involves collecting data to understand the efficacy and use of DEWS tools. Data collection will be undertaken by the ARC team at the facility level. This will include the completion of DEWS tools and audit data of completed DEWS tools. All audit data and clinical data shared with investigators will not be identifiable. There will be no sharing of data between ARC facility teams maintaining confidentiality.
* Meeting documentation: Records will be kept of regular support meetings (including members from all participating ARC facilities) in the form of meeting minutes. Meetings will be conducted on-line (via zoom) no electronic recordings of the meeting will be made. Minutes will be confidential to meeting participants and the research team. Learnings from meetings may be shared with participating ARC facilities and their healthcare staff teams.
* Evaluation staff interviews / surveys: Evaluation interviews will be conducted with healthcare staff. The content of individual interviews / focus groups is confidential to the research team and will not be shared with the employing organisation. The data will be collated and examined for themes. Themes from the interview will inform the project evaluation.
* Informed consent

Organisation consent will be obtained for the feasibility study. We will not be seeking individual healthcare staff consent for the DEWS feasibility study as recognising and responding to acute deterioration is a core expectation that cannot be ‘opted out’, this feasibility study does not change that expectation. It is expected that ARC project teams engage their staff in education and improvement activities, providing an opportunity to ask questions, raise concerns and come to a shared understanding of the process.

Individual healthcare staff consent will be required for participation in evaluation interviews. Healthcare staff are all adults with the capacity to comprehend and consent. Participation in evaluation will be entirely voluntary.

* Conflict of interest / power relationships

Te Tāhū Hauora is a statutory body tasked with supporting quality and systems improvement in collaboration with clinical teams. Recruitment will be done by advertisement distributed by the Quality Leads group avoiding the perception of coercion.

* Right to withdraw

All participating ARC facilities have the right to withdraw at anytime without explanation. Any data that can be traced to that facility or individual can also be withdrawn. At the point of final evaluation where data from all ARC facilities is collated into one data set there will no longer be an option to withdraw information.

**DATA STORAGE:**

**Audit data.** All audit data will be non-identifiable.It will be collected by the individual ARC facility using an electronic data collection form created using Microsoft Forms (MS Forms). The data collection form will be created and owned by Te Tāhū Hauora. MS Forms is encrypted software, which prevents unauthorised access to digital information both at rest and during transfer. Each ARC facility will collect their own data and load it into the MS form on a weekly basis. This is a data entry point only, users cannot view or change data previously entered. Users will reach the form via electronic link. Once data is added to the form a specific allocated personal identification number (PIN) allocated to the participating ARC facility is required for submission. If the PIN is not validated a research team member will contact the participating ARC facility to query data entry. If it is not possible to verify that the form is authentic the results of that audit will be disregarded.  Validated data is exported and stored in a secure electronic folder owned by Te Tāhū Hauora. Data is accessible by the research team only and is password protected. Weekly reports will be created from the data entered using Microsoft Power BI. This report of aggregated data will be shared with the research team and each ARC facility. Individual ARC facilities will see own data only. This report is to inform DEWS implementation process.

**Other data** (field notes, meeting minutes, focus group / individual interviews, survey data) will be stored in a secure share point electronic folder owned by Te Tāhū Hauora. The folder will be password protected and accessible to the research team only. Meeting minutes and fieldnotes will contain names of participating healthcare staff and facilities. Interview data will not identify individuals but will identify participating ARC facilities.

**Data backup:** All data is backed up locally in the Revera data centre, which host our servers.

**Data destruction:** Data will be kept for 6 years. Deliberate destruction of data occurs as per the Te Tāhū Hauora General Disposal Authority policy. Retention and destruction schedules are applied automatically to all labelled data when that data reaches its destruction date.  Reports are generated before destruction, and once approved, only then is the data destroyed. Records of all data destruction are retained

## **L: RISKS and BENEFITS OF PARTICIPATION**

## **Benefits**

## Staff capability

## This is a quality improvement project to implement and clinical assessment and communication tool. As part of participation ARC staff will be provided with resident assessment and clinical communication skills training. Alongside the clinical aspects of this feasibility study key members of ARC staff will lead out the local quality improvement processes increasing the quality improvement capability of the ARC team.

Continuous Quality improvement

* This is key expectation of health providers and this feasibility study can contribute to ARC fulfilling its Health and Disability Sector Standards expectations. As residents and their whānau / families become aware of the project being seen to be focused on the clinical safety of their residents may have a positive impact on the reputation of the facility.

## Potential for increased resident safety

* The DEWS is designed to support healthcare staff to recognise and respond (R&R) to acute deterioration. The hypothesis is that R&R will occur in a more timely manner and that may prevent further deterioration of residents with reversible conditions or enable more time to accomplish peaceful anticipated dying. Both scenarios would increase resident safety. At worst the feasibility study will be non-inferior to current practice and will refocus staff on monitoring resident condition.

Sector wider potential benefits

* If the DEWS feasibility study evaluation demonstrates the effectiveness of the process. The participating facilities will a) get to influence the tools and implementation processes so they best match ARC sector realities b) provide an evidence based evaluation of whether implementation of DEWS is warranted c) identify areas of further research that add value to the ARC sector

## **Risks**

## This feasibility study focuses on healthcare staff. It tests a standardised system to support ARC healthcare staff to recognise and respond to the acute deterioration. Recognising and responding to acute deterioration is a core clinical practice expectation that is unchanged by this project. The DEWS tools do not replace clinical judgement, they supplement and support exiting clinical decision making and escalation pathways. As is standard practice health professionals remain responsible for their clinical judgement and practice.

DEWS tools

* The DEWS tools are newly developed. They are based on the best available evidence. Tools with similar components (vitals sign tools and non-specific signs tools) have been tested in overseas ARC facilities and have been non-inferior. It is possible that DEWS will over estimate acute deterioration and result in increased contact with the primary care provider (and potentially increased costs). It is possible (but less likely) that DEWS will underestimate acute deterioration. The DEWS does not replace clinical judgement education documentation will emphasise that healthcare stuff should escalate any resident situation causing them concern

Workforce

* Feasibility study testing the DEWS requires practice change and assimilation of new ways of working. Change can be unsettling and may impacted on staff wellbeing. Facilities will be asked to monitor the effects of change on the wellbeing of their staff.

COVID-19 Pandemic

* The pandemic is ongoing and there this potential for staff sickness. The project team will minimise risk to ARC facilities by complying with their infection control procedures during site visits. Participants with symptoms of viral infections will be asked to stay away from in-person activities. In the event of a lock down this project will move to a fully on-line process.

Potential consumer impact

* Residents and their whānau / families may be aware of staff using DEWS tools, this may raise questions, comments, concerns from consumers to ARC providers. ARC providers will be encouraged to share openly that they are participating in the DEWS feasibility study. No increased exposure to clinical intervention is anticipated for the resident.

Potential impact on relationship with other services

* The DEWS feasibility study includes taking stock of currently escalation processes in the event of acute deterioration. A change or formalisation of escalation processes with primary care provider may be required / desired.
* When talking to other (external providers) references to “DEWS” by ARC staff may cause confusion. To help mitigate this the Expert Advisory Group will include representative for key stakeholder groups.

### M. DISSEMINIATION AND INTELLECTURAL PROPERTY

The Project Leadership Team will complete the evaluation report and any subsequent publications. The intellectual property of this feasibility study is jointly held with the Project Leadership Team. However the copyright and intellectual proper to of DEWS tools and supporting clinical documents (education & guideline) belongs to Daltrey and Boyd and no changes, copying or dissemination of the DEWS is permitted without authorisation.

The evaluation report will be disseminated through Te Tāhū Hauora usual processes. Academic publications (conference, journal, thesis) will lead by Daltrey and Boyd. Te Tāhū Hauora will be acknowledged on all reports.

### N LIST OF SUPPORTING DOCUMENTS

**Project enrolment**

* Recruitment advertising
* Participant information sheets (ARC executive leadership)
* Participant information sheets (evaluation interviews)
* Consent form, authority to access ARC (ARC executive leadership)
* Consent form evaluation interviews

**Project progress**

* Letter of support Ahuahu Kaunuku
* Terms of reference Executive Advisory Group
* A guide to preparing and implementing the Deterioration Early Warning System | He aratohu hei whakarite pūnaha kitenga wawe i te āhua tauheke”
  + Escalation mapping tool
  + Project charter template
  + Current status assessment tool
* DEWS Tools (Quick DEWS, DEWS – RN Assessment, SBARR-DEWS communication tool)

**Project evaluation**

* Semi-structured interviews schedule (ARC quality leads & ARC user group)
* Survey (HCA & RN & primary care)
* Project costs template
* Quality improvement knowledge evaluation
* Audit information

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