

FOCUS: The Frailty Outcomes Consensus Project

Study Findings & Potential Applications

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Canadian Frailty Network (CFN)

Who are we?

- Not-for-profit pan-Canadian network since 2012
- Funded by the federal government through Networks of Centres of Excellence
- Multi-disciplinary network which includes investigators, stakeholders, trainees, partners, citizens, and caregivers



What do we do?

- We aim to improve care for older adults living with frailty and to support their family and friend caregivers

FOCUS Project Background

Care providers and decision makers often face difficult decisions when treating persons living with frailty but high quality evidence for decision making is often lacking

Evidence is lacking because:

- Persons living with frailty are often excluded from trials
- Trials enrolling older adults rarely consider differential impact of frailty
- Few frailty clinical trials

FOCUS Project Background

Because of the lack of evidence:

- Treatments that are effective in fit patients are often applied to persons living with frailty
 - May not be effective
 - May result in harm or wasted resources
- Possibility that therapies/interventions not effective in fit patients may be effective in those who are living with frailty

FOCUS Project Objective

- To identify a set of core data elements and core outcome measures for frailty
 - Will enable findings from research and translational studies to be collectively analyzed to better inform patient care

What are CDEs and COMs?

- **Core data elements (CDEs):**

- Minimum baseline study population descriptors that would be collected on study participants in all frailty studies. Measures of frailty would be derived from the baseline data collected.

- **Core outcome measures (COMs):**

- Outcomes that would be measured in all frailty trials as a minimum. Investigators would be free to measure study specific outcome measures as required.

Methods

Consultation

- Input from older adults, persons living with frailty, unpaid and paid caregivers via survey
- Online survey distributed broadly to CFN members and others to provide input regarding possible additional items

Literature Review

- Identifies outcomes reported in RCTs

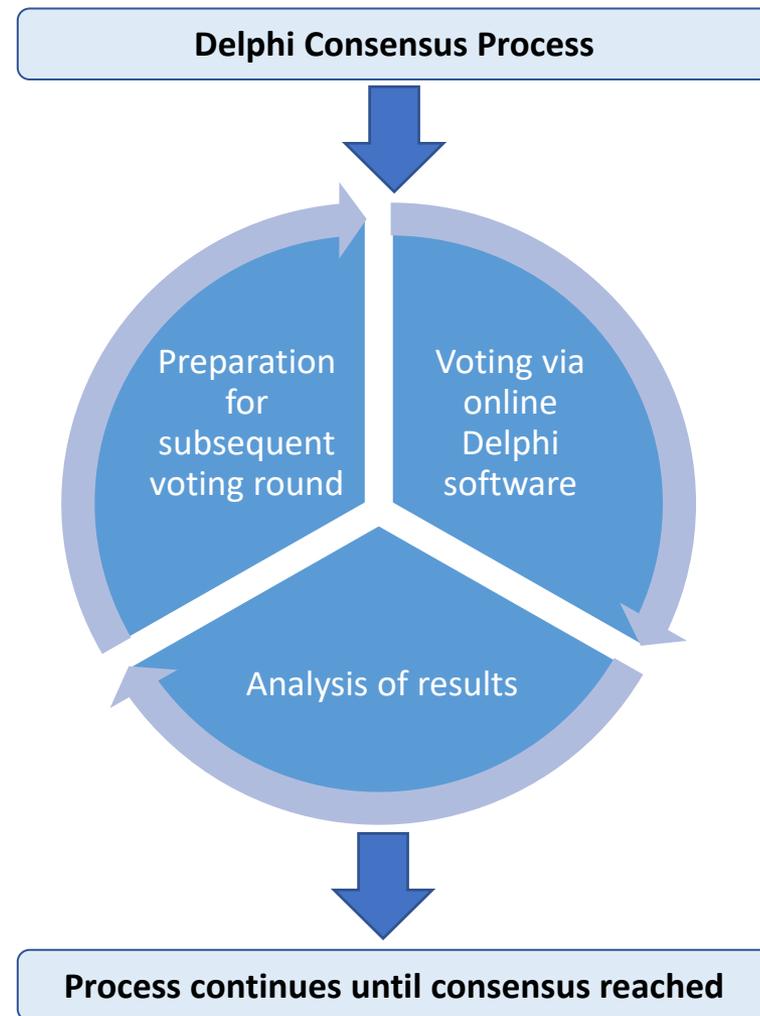
Results and Input Summarized

Finalized list of CDEs and COMs for Delphi Panelists

Delphi Consensus Process

Methods

- Project steering committee convened to guide Delphi process
 - Dr. Beverly Shea
 - Dr. Darryl Rolfson
 - Dr. Leocadio Rodriguez Manas
 - Dr. Matteo Cesare
 - Dr. Paula Williamson
 - Dr. John Muscedere
- Panelists:
 - Researchers
 - Clinicians
 - Policymakers
 - Older adults
 - Family/friend caregivers



How did participants score CDEs/COMs?

- Score each outcome or data element on a scale from 1-9, based on how **important you feel the outcome or data element is to include** in the frailty common outcome/data element set
 - **1-3 not important**
 - **4-6 important but not critical**
 - **7-9 critical to include**

Participants:

	Healthcare Professionals	Older Adults	Caregivers
Round 1	165	8	11
Round 2	139	7	8*
Round 3	113	6	7

- A priori, steering committee had agreed up a required min. 80% participant retention between rounds [* 1 caregiver passed away during the course of the study; therefore the caregiver denominator was 10 for round 2]
- Participants represented 25 countries
- Approximately 60% of sample was Canadian

Consensus Criteria

- 1. Consensus that a data element/outcome is important for a core domain set: $\geq 80\%$ of participants in all groups scored the item as "critically important to include in a core set" (score 7 to 9) and $\leq 10\%$ score as 1-3; these items are acknowledged in subsequent rounds as having met criteria for importance to a core set, and held for final round discussion.
- 2. Consensus that a data element/outcome will NOT be included : $\geq 50\%$ of participants in all groups scored the item as of "limited importance" (score 1 to 6); these items are dropped from Delphi and are not be part of core set.

Consensus Criteria

- 3. Dissensus but important to one group: 80%+ participants in one of our groups score items as critically important for a core set (score 7 to 9); data element/outcome continues on to next round as having no consensus yet; if data element/outcome does not reach consensus level at end of Delphi, but still important to one group, it will be held for final round discussion.
- 4. No consensus: All other results; data element/outcome continues to next round as having no consensus yet. If data element/outcome does not achieve consensus by last round, and no groups have supported it $\geq 80\%$, then data element/outcome is not endorsed for core set.

Ranking Round

- Concerns regarding measurement burden and feasibility of implementation of such a large set led to a ranking round of CDEs and COMs
- Participants were invited to rank their **top 2** CDEs or COMs in any domain where 2 or more items had met consensus criteria in round 3
- The top-ranked CDE or COM in each domain would form the core set; 2nd would form supplementary set

Dissemination & Application of Frailty Core Set



Canadian
Frailty
Network

Réseau canadien
des soins aux
personnes fragilisées



NCE RCE

Example of Potential Application

- A primary care clinical commissioning group in the UK is exploring outcome selection in clinical services
- Frailty identified as priority area
- Want an evidence-based and patient-centred approach

Example of Potential Application

- Local consultation is an important part of commissioning
 - Will convene a panel of local stakeholders (patients, carers, clinicians, service providers, NHS managers) to review the outcomes and measures within FOCUS set to be used
- FOCUS will be used as the basis for discussion for choosing outcomes for their framework

Thank you!

