Core Outcomes for Clinical Research in Acute Respiratory Failure Survivors

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Create and nationally disseminate resources to assist Acute Respiratory Distress Syndrome (ARDS)/Acute Respiratory Failure (ARF) researchers in designing trials that appropriately evaluate long-term patient outcomes

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R24 Grant Aims

Aim 1: Web-based electronic database of validated and recommended survey instruments and clinical testing methods for long-term outcomes

Aim 2: Practical resources for maximizing retention in long-term, longitudinal research

Aim 3: Statistical methods & programs for evaluating functional outcomes in the presence of high patient mortality ("competing risk of mortality")

Outcome measurement in ICU survivorship research from 1970-2013: a scoping review of 425 publications

Turnbull et al. *Crit Care Med*. 2016;44:1267-77

Peer-reviewed published studies 1970 - 2013

- ≥ 20 adult ICU survivors assessed after hospital discharge

Excluded

- Qualitative studies
- Studies only assessing survival
- Psychometric evaluations of measurement instruments or tests
- >50% of patients had neurologic injury
- >50% of patients had cardiac surgery

Outcome measurement in ICU survivorship research from 1970-2013: a scoping review of 425 publications

Turnbull et al. *Crit Care Med*. 2016;44:1267-77

425 peer-reviewed papers

- Outcomes assessed using 250 different measurement instruments

Why is this a problem?

- Difficult to compare results
- Barrier to meta-analyses
- Selective outcome reporting bias

Our goal

Develop a core set of outcomes and related measures for survivors of acute respiratory failure (including ARDS) after hospital discharge using a rigorous methodology and an international panel of relevant stakeholders.

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Definitions

- **Core outcome** - a concept, health-related condition, or aspect of health that must always be measured within a specific field of research

  (***What** outcomes should we all measure?)*

- **Core measure** – a measurement instrument selected to assess a core outcome

  *(**How** should we measure them?)*

CORE MEASURE SET (CMS)

Core measure set: A minimum collection of agreed-upon measures (for core outcomes) reported in all studies within a specific field.

A CMS does NOT prevent investigators from collecting data on additional outcomes.

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Work informing CMS development

- Scoping review
- Systematic reviews
- Psychometric evaluations of existing instruments
- Qualitative interviews with ARDS survivors

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Modified Delphi Consensus Process

Uses expert opinion to address questions for which empirical data are unavailable or inadequate

Delphi – Expert Panel

Stakeholder groups

1. Clinical researchers (n=35)
   i. All International Forum for Acute Care Trialists (InFACT) members
   ii. Random sample of 6 corresponding authors from scoping review
   iii. 9 authors of internationally recognized ARF research
   iv. >16 countries represented
2. Clinicians/professional associations (n=19)
   i. ICU physicians, ICU nurses, rehabilitation clinicians
   ii. Australia, Canada, UK, & US
3. Patients/caregivers (n=17)
   i. Australia, Canada, UK, & US
4. Funding bodies (n=4)

Delphi Methodology

- Each outcome rated using GRADE scale

  (1 – 3) = Not Important

  (4 – 6) = Important but not Critical

  (7 – 9) = Critical

  Unable to score

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Delphi Methodology

***a priori* consensus definition**

≥70% rated outcome as Critical (≥7)

And

≤15% rated outcome as Not important (≤3)

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Delphi Methodology

1. All voting conducted online
2. Anonymity maintained
3. No consideration of the availability, ease of use, feasibility, or properties of available instruments

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Phase I: Round 1

Before voting, review:

- Survey of corresponding authors of publications regarding potential core outcomes
- Phone-based survey of ARF survivors and caregivers about potential core outcomes
- Summary of qualitative study of ARF survivors regarding key outcomes

Phase I: Round 1

Then:

- Rate each of 19 preliminary outcomes from
  - Patient Reported Outcome Measurement Information System (PROMIS)
  - WHO's International Classification of Functioning, Disability, & Health (ICF)
  - SCCM's Post-Intensive Care Syndrome (PICS) framework
  - Clinician, researcher and patient input
- Option of proposing additional outcomes

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Phase I: Round 1 - Results

- 96% participation rate
- 7 outcomes met consensus criteria
- 8 new outcomes suggested
- No outcomes dropped from consideration

Round 1 Survey Results by Stakeholder Group (96% response rate)

	Score	Proportion of stakeholders rating the outcome ≥7 on a 9-point Likert scale				
Outcomes	Mean (SD) (n=74)	All Panel Members (n=74)	Clinical Researchers (n=33)	Clinicians / Professional Associations (n=19)	Patients and Caregivers (n=18)	US Federal Research Funding Organizations (n=4)
Outcomes meeting consensus criteria[a]						
Cognitive function and symptoms	8.1 (1.1)	68 (92%)	32 (97%)	18 (95%)	14 (78%)	4 (100%)
Physical function and symptoms	8.1 (1.0)	66 (89%)	30 (91%)	17 (89%)	15 (83%)	4 (100%)
Mental health conditions and symptoms	7.9 (1.0)	64 (86%)	30 (91%)	16 (84%)	14 (78%)	4 (100%)
Survival	7.9 (1.6)	56 (76%)	31 (94%)	14 (74%)	9 (50%)	2 (50%)
Pain	7.2 (1.5)	54 (73%)	23 (70%)	15 (79%)	13 (72%)	3 (75%)
Muscle and/or nerve function	7.3 (1.5)	52 (70%)	23 (70%)	12 (63%)	13 (72%)	4 (100%)
Pulmonary function and symptoms	7 (1.6)	52 (70%)	20 (61%)	14 (74%)	15 (83%)	3 (75%)
Outcomes not meeting consensus criteria[b]						
Satisfaction with life, or personal enjoyment	7.1 (1.4)	51 (69%)	21 (64%)	14 (74%)	14 (78%)	2 (50%)
Return to work or prior activities	6.9 (1.6)	45 (61%)	24 (73%)	11 (58%)	8 (44%)	2 (50%)
Fatigue	6.8 (1.7)	44 (59%)	20 (61%)	11 (58%)	11 (61%)	2 (50%)
Impact on family and/or caregivers	6.7 (1.7)	40 (54%)	17 (52%)	11 (58%)	11 (61%)	1 (25%)
Swallowing function and symptoms	6.4 (1.8)	37 (50%)	15 (45%)	9 (47%)	11 (61%)	2 (50%)
Financial impact on patient	6.2 (1.9)	35 (47%)	13 (39%)	7 (37%)	14 (78%)	1 (25%)
Healthcare resource utilization	6.3 (1.7)	35 (47%)	16 (48%)	5 (26%)	12 (67%)	2 (50%)
Sleep function and symptoms	6.3 (1.6)	35 (47%)	16 (48%)	7 (37%)	10 (56%)	2 (50%)
Social roles, activities or relationships	6.3 (1.8)	34 (46%)	17 (52%)	7 (37%)	9 (50%)	1 (25%)
Type of residence	6.2 (1.8)	32 (43%)	13 (39%)	10 (53%)	8 (44%)	1 (25%)
Gastrointestinal function and symptoms	5.5 (1.8)	21 (28%)	7 (21%)	5 (26%)	7 (39%)	2 (50%)
Sexual function and symptoms	4.8 (1.8)	11 (15%)	3 (9%)	2 (11%)	5 (28%)	1 (25%)

[a] The consensus criteria for inclusion as a core outcome was defined as ≥70% of all panel members rating an outcome ≥7 and no more than 15% rating the outcome ≤3 on a 9-point scale. Outcomes are ordered by the proportion of panel members rating the outcome ≥7.

[b] A total of 7 of 74 (9%) unique panel members ever selected "Unable to Score." The number of panel members selecting "Unable to Score" by outcome: Physical function and symptoms (1), Mental health conditions and symptoms (1), Survival (3), Muscle and/or nerve function (1), Pulmonary function and symptoms (1), Return to work or prior activities (3), Impact on family and/or caregivers (3), Swallowing function and symptoms (2), Healthcare resource utilization (1), Sleep function and symptoms (1), and Social roles, activities or relationships (1).

Phase I: Round 2

Before voting, review:

Your Round 1 response compared to:

- aggregate responses for the entire panel
- aggregate responses of each stakeholder group

Phase I: Round 2

Then :

Rate each of 19 preliminary outcomes and the 8 newly suggested outcomes

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Phase I: Round 2 - Results

- 97% participation rate
- 7 outcomes met consensus inclusion criteria
- No newly suggested outcomes met inclusion criteria

Table 3: Round 2 Survey Results by Stakeholder Group

	Score	Proportion of stakeholders scoring the outcome ≥7 on a 9-point Likert scale				
Outcome	Mean (SD) (n=75)	All Panel Members (n=75)	Clinical Researchers (n=35)	Clinicians / Professional Associations (n=19)	Patients and Caregivers (n=17)	US Federal Research Funding Organizations (n=4)
Outcomes meeting consensus criteria[a]						
Physical function and symptoms	8.4 (0.8)	73 (97%)	34 (97%)	18 (95%)	17 (100%)	4 (100%)
Cognitive function and symptoms	8.4 (0.9)	71 (95%)	34 (97%)	18 (95%)	15 (88%)	4 (100%)
Mental health conditions and symptoms	8.0 (0.8)	70 (93%)	33 (94%)	18 (95%)	15 (88%)	4 (100%)
Survival	8.2 (1.3)	64 (85%)	35 (100%)	16 (84%)	10 (59%)	3 (75%)
Pulmonary function and symptoms	7.3 (1.4)	64 (85%)	29 (83%)	14 (74%)	17 (100%)	4 (100%)
Pain	7.5 (1.1)	63 (84%)	29 (83%)	17 (89%)	14 (82%)	3 (75%)
Muscle and/or nerve function	7.3 (1.2)	62 (83%)	27 (77%)	16 (84%)	15 (88%)	4 (100%)
Outcomes not meeting consensus criteria[a]						
Satisfaction with life, or personal enjoyment	7.2 (1.2)	52 (69%)	22 (63%)	14 (74%)	14 (82%)	2 (50%)
Impact on family and/or caregivers	7.1 (1.4)	50 (67%)	23 (66%)	12 (63%)	13 (76%)	2 (50%)
Fatigue	6.9 (1.4)	49 (65%)	23 (66%)	12 (63%)	12 (71%)	2 (50%)
Return to work or prior activities	7.0 (1.3)	48 (64%)	23 (66%)	13 (68%)	10 (59%)	2 (50%)
Swallowing function and symptoms	6.7 (1.6)	47 (63%)	20 (57%)	11 (58%)	13 (76%)	3 (75%)
Financial impact on patient	6.7 (1.5)	43 (57%)	19 (54%)	8 (42%)	15 (88%)	1 (25%)
Healthcare resource utilization	6.6(1.2)	41 (55%)	20 (57%)	7 (37%)	12 (71%)	2 (50%)
Sleep function and symptoms	6.4 (1.4)	38 (51%)	17 (49%)	7 (37%)	12 (71%)	2 (50%)
Social roles, activities or relationships	6.6 (1.3)	37 (49%)	19 (54%)	6 (32%)	11 (65%)	1 (25%)
Type of residence	6.3 (1.6)	30 (40%)	12 (34%)	9 (47%)	8 (47%)	1 (25%)
Gastrointestinal function and symptoms	5.5 (1.5)	16 (21%)	4 (11%)	5 (26%)	6 (35%)	1 (25%)
Sexual function and symptoms	4.9 (1.2)	7 (9%)	3 (9%)	0 (0%)	4 (24%)	0 (0%)
Outcomes suggested by stakeholders during Round 1 (none meeting consensus criteria[a])						
Fatigability / endurance	6.9 (1.4)	47 (63%)	19 (54%)	12 (63%)	14 (82%)	2 (50%)
Susceptibility to repeated infections	6.7 (1.5)	46 (61%)	17 (49%)	12 (63%)	14 (82%)	3 (75%)
Renal Function	6.5 (1.5)	42 (56%)	17 (49%)	9 (47%)	14 (82%)	2 (50%)
Self-efficacy/management	6.4 (1.7)	36 (48%)	16 (46%)	7 (37%)	10 (59%)	3 (75%)
Management of Complex Medication Regimens	6.2 (1.7)	35 (47%)	13 (37%)	10 (53%)	11 (65%)	1 (25%)
Resilience	6.4 (1.7)	34 (45%)	14 (40%)	6 (32%)	12 (71%)	2 (50%)
Hearing	5.8 (1.6)	23 (31%)	14 (40%)	3 (16%)	3 (18%)	3 (75%)
Loss of Taste	5.6 (1.6)	18 (24%)	10 (29%)	3 (16%)	4 (24%)	1 (25%)

Abbreviations: SD, Standard Deviation

[a] The consensus criteria for inclusion as a core outcome was defined as ≥70% of all panel members rating a outcome ≥7 and no more than 15% rating the outcome ≤3 on a 9-point scale. Outcomes are ordered by the proportion of panel members rating the outcome ≥7.

[b] A total of 4 of 75 (5%) unique panel members ever selected "Unable to Score." Number of panel members selecting "Unable to Score" by outcome: Survival (1), Impact on family and/or caregiver (1), Hearing (1), and Management of complex medication regimens (1).

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Table 3: Round 2 Survey Results by Stakeholder Group

Outcome	Score: Mean (SD) (n=75)	Proportion of stakeholders scoring the outcome ≥7 on a 9-point Likert scale: All Panel Members (n=75)	Clinical Researchers (n=35)	Clinicians / Professional Associations (n=19)	Patients and Caregivers (n=17)	US Federal Research Funding Organizations (n=4)
Outcome meeting consensus criteria[a]						
Physical function and symptoms	8.4 (0.8)	73 (97%)	34 (97%)	18 (95%)	17 (100%)	4 (100%)
Cognitive function and symptoms	8.4 (0.9)	71 (95%)	34 (97%)	18 (95%)	15 (88%)	4 (100%)
Mental health conditions and symptoms	8.0 (0.8)	70 (93%)	33 (94%)	18 (95%)	15 (88%)	4 (100%)
Survival	8.2 (1.3)	64 (85%)	35 (100%)	16 (84%)	10 (59%)	3 (75%)
Pulmonary function and symptoms	7.3 (1.4)	64 (85%)	29 (83%)	14 (74%)	17 (100%)	4 (100%)
Pain	7.5 (1.1)	63 (84%)	29 (83%)	17 (89%)	14 (82%)	3 (75%)
Muscle and/or nerve function	7.3 (1.2)	62 (83%)	27 (77%)	16 (84%)	15 (88%)	4 (100%)
Outcomes not meeting consensus criteria[a]						
Satisfaction with life, or personal enjoyment	7.2 (1.2)	52 (69%)	22 (63%)	14 (74%)	14 (82%)	2 (50%)
Impact on family and/or caregivers	7.1 (1.4)	50 (67%)	23 (66%)	12 (63%)	13 (76%)	2 (50%)
Fatigue	6.9 (1.4)	49 (65%)	23 (66%)	12 (63%)	12 (71%)	2 (50%)
Return to work or prior activities	7.0 (1.3)	48 (64%)	23 (66%)	13 (68%)	10 (59%)	2 (50%)
Swallowing function and symptoms	6.7 (1.6)	47 (63%)	20 (57%)	11 (58%)	13 (76%)	3 (75%)
Financial impact on patient	6.7 (1.5)	43 (57%)	19 (54%)	8 (42%)	15 (88%)	1 (25%)
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Sleep function and symptoms	6.4 (1.4)	38 (51%)	17 (49%)	7 (37%)	12 (71%)	2 (50%)
Social roles, activities or relationships	6.6 (1.3)	37 (49%)	19 (54%)	6 (32%)	11 (65%)	1 (25%)
Type of residence	6.3 (1.6)	30 (40%)	12 (34%)	9 (47%)	8 (47%)	1 (25%)
Gastrointestinal function and symptoms	5.5 (1.5)	16 (21%)	4 (11%)	5 (26%)	6 (35%)	1 (25%)
Sexual function and symptoms	4.9 (1.2)	7 (9%)	3 (9%)	0 (0%)	4 (24%)	0 (0%)
Outcomes suggested by stakeholders during Round 1 (none meeting consensus criteria[a])						
Fatigability / endurance	6.9 (1.4)	47 (63%)	19 (54%)	12 (63%)	14 (82%)	2 (50%)
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Loss of Taste	5.6 (1.6)	18 (24%)	10 (29%)	3 (16%)	4 (24%)	1 (25%)

Abbreviations: SD, Standard Deviation

[a] The consensus criteria for inclusion as a core outcome was defined as ≥70% of all panel members rating a outcome ≥7 and no more than 15% rating the outcome ≤3 on a 9-point scale. Outcomes are ordered by the proportion of panel members rating the outcome ≥7.

[b] A total of 4 of 75 (5%) unique panel members ever selected "Unable to Score." Number of panel members selecting "Unable to Score" by outcome: Survival (1), Impact on family and/or caregiver (1), Hearing (1), and Management of complex medication regimens (1).

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Outcomes meeting consensus criteria[a]						
Physical function and symptoms	8.4 (0.8)	73 (97%)	34 (97%)	18 (95%)	17 (100%)	4 (100%)
Cognitive function and symptoms	8.4 (0.9)	71 (95%)	34 (97%)	18 (95%)	15 (88%)	4 (100%)
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Abbreviations: SD, Standard Deviation

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Differing stakeholder perspectives

Outcome	Clinical Researchers (n=35)	Clinicians / Professional Associations (n=19)	Patients and Caregivers (n=17)	US Federal Research Funding Organizations (n=4)
Financial impact on patient	19 (54%)	8 (42%)	15 (88%)	1 (25%)
Healthcare resource utilization	20 (57%)	7 (37%)	12 (71%)	2 (50%)

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CORE OUTCOMES

1. Survival
2. Satisfaction with life, or personal enjoyment
3. Physical function and symptoms
4. Cognitive function and symptoms
5. Mental health conditions and symptoms
6. Pulmonary function and symptoms
7. Pain
8. Muscle and/or nerve function

PHASE I results

Turnbull AE, Sepulveda KA, Dinglas VD, Bingham CO, Needham, DM. **Core Domains for Clinical Research in Acute Respiratory Failure Survivors: An International Modified Delphi Consensus Study**. *Critical Care Medicine*. 2017; *In Press*.

If you're planning a study of ARF survivors:

Contact us!

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