ORIGINAL ARTICLE

Perspectives of survivors, families and researchers on key outcomes for research in acute respiratory failure

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ABSTRACT

Background There is heterogeneity among the outcomes evaluated in studies of survivors of acute respiratory failure (ARF).

Aim To evaluate the importance of specific outcome domains to acute respiratory distress syndrome (ARDS) survivors, their family members and clinical researchers.

Methods Nineteen outcome domains were identified from the National Institutes of Health's Patient Reported Outcomes Measurement Information System; WHO's International Classification of Functioning, Disability, and Health; Society of Critical Care Medicine's Post-Intensive Care Syndrome (PICS); as well as patient, clinician and researcher input. We surveyed ARDS survivors, family members and critical care researchers, 279 respondents in total, using a 5-point scale (strongly disagree, disagree, neutral, agree and strongly agree) to rate the importance of measuring each domain in studies of ARF survivors' postdischarge outcomes.

Measurements and main results At least 80% of patients and family members supported (ie, rated 'agree' or 'strongly agree') that 15 of the 19 domains should be measured in all future studies. Among researchers, 6 of 19 domains were supported, with researchers less supportive for all domains, except survival (95% vs 72% support). Overall, four domains were supported by all groups: physical function, cognitive function, return to work or prior activities and mental health.

Conclusion Patient, family and researcher groups supported inclusion of outcome domains that fit within the PICS framework. Patients and family members also supported many additional domains, emphasising the importance of including patients/family, along with researchers, in consensus processes to select core outcome domains for future research studies.

Key messages

What is the key question?

► Among acute respiratory distress syndrome (ARDS) survivors, their family members and clinical researchers, which posthospital outcome domains are considered critical to measure in all research studies of acute respiratory failure (ARF)?

What is the bottom line?

► ARDS survivors, their family members and clinical researchers all support measuring physical function, cognitive function, mental health and return to work or prior activities in all studies of ARF survivors.

Why read on?

► Given the heterogeneity among outcomes reported in studies of ARF, understanding which outcome domains are important to each stakeholder group (patient, family and researchers) is a critical initial step toward creating a minimum set of core outcome measures to evaluate in all future studies.

INTRODUCTION

Survivors of acute respiratory failure (ARF), including those with acute respiratory distress syndrome (ARDS), experience long-term impairments in physical, cognitive and mental health outcomes.[1–4] Consequently, professional organisations, research funding agencies and clinical researchers have emphasised the importance of measuring patient outcomes beyond short-term survival.[5–10] An increasing number of studies have evaluated postdischarge outcomes in survivors, although evaluating many different patient outcome domains using many different outcome measures to assess each domain.[11]

To address this heterogeneity in the patient outcomes reported in clinical research studies and to facilitate the ability to compare results and synthesise data, creating a 'core outcome set' for clinical research evaluating survivors of ARF has been recommended.[12 13] A core outcome set is defined as the minimum set of outcome measures always reported in studies within a specific field.[14 15] An important step toward creating a core outcome set is understanding which outcome domains (ie, outcomes, health conditions or other aspects of health)[16] are considered important by relevant stakeholders, including patients, family members and researchers. Hence, we surveyed each of these stakeholder groups to obtain their view regarding the importance of measuring specific outcome domains in all clinical studies evaluating ARF patient outcomes after hospital discharge.

METHODS

Patient and family members

Patients included in this study were recruited from the national, multicentre Statins for Acutely Injured

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Lungs (SAILS) randomised controlled trial,[17] after completion of their final 12-month follow-up assessment for the ARDS Network Long-Term Outcomes Study (ALTOS).[18] To be eligible for inclusion, at the time of this study, patients needed to be alive with a working phone number and able to participate (eg, not incarcerated or hospitalised). Regardless of patient eligibility, family members of ALTOS-SAILS study patients were eligible to participate if they had a working phone number (eg, family members could participate even if the patient had died).

Clinical researchers

Clinical researchers included in this study were recruited from a pre-existing international database of corresponding authors of 425 articles included in a scoping review of clinical research evaluating intensive care unit (ICU) survivor outcomes after hospital discharge.[11] This international pool of researchers was invited to complete the survey if they listed an email address in their publication. When a listed email address was outdated, we searched online (eg, search engines, PubMed) and via colleagues to obtain an updated email address.

Survey design

A total of 19 outcome domains were identified for evaluation in this survey via review of the following patient outcomes frameworks: National Institutes of Health's Patient Reported Outcomes Measurement Information System (PROMIS),[19] WHO's International Classification of Functioning, Disability, and Health,[20] and Society of Critical Care Medicine's Post-Intensive Care Syndrome (PICS),[8 21] along with specific review and input from patients, clinicians and researchers. Names and descriptions of the 19 domains were adapted for clarity for patients and family members and for internal consistency (eg, consistent use of 'function/symptoms' as part of domain name).

The 19 outcome domains (see online supplementary file 1) were included in a survey instrument to evaluate the level of support for requiring measurement of the domain within a minimum set of domains to be assessed in all studies of posthospital survivorship in ARF patients. The survey was extensively pilot tested with patients, caregivers and clinicians, as well as via two separate modified Delphi Consensus processes conducted with participants at multidisciplinary clinician/researcher conferences held in the USA (n=100 for online survey and n=44 for subsequent in-person meeting) and in Australia (n=85 for in-person meeting).[22] From this pilot testing, no additional domains were suggested to be added to the list included in the survey instrument for the current study. However, based on this pilot testing, the domain originally called 'Health-related quality of life (Satisfaction with life, personal enjoyment)' was re-named 'Satisfaction with life, or personal enjoyment' to help respondents evaluate the importance of the domain, alone, without considering well-known instruments that measure this domain. In addition, response options were revised from four options ('must always measure', 'sometimes should measure', 'not important to measure' and 'unsure') to five options ('strongly disagree', 'disagree', 'neutral', 'agree' and 'strongly agree').

In addition to the above pilot testing, to ensure completeness of the domains being evaluated, in this survey instrument, patients, family and researchers were specifically asked if any domains were missing from the list of 19 domains they were asked to rate. Moreover, patients and family members were asked whether they would have rated each domain differently if they had been surveyed at 6 months after ICU, rather than the actual timing of the survey administration.

Patient and family surveys were administered via phone, with specific instruction to consider whether each outcome domain was important to be measured in all research studies of critical care survivors. The international cohort of clinical researchers received a similar web-based survey (Qualtrics, Provo, Utah). Completion of the survey indicated informed consent to participate by patients, family members and researchers. The Johns Hopkins Medical Institutions' institutional review board approved this study.

Statistical analyses

Stacked bar graphs were used to visualise response distribution for all 19 domains (see online supplementary figure 1). A respondent was defined as 'supporting' a domain if he/she selected 'agree' or 'strongly agree' for the domain. For each of the 19 domains, the proportion of respondents who supported the domain was compared for patients versus family members using general estimating equations with binary distribution (logistic regression) adjusting for clustering of patient–family dyads. For two domains, the models would not converge, and a Poisson model was used instead. For patients versus researchers comparison, we used Fisher's exact test. The margin of error for each proportion was calculated at 95% confidence level.[23] For patient–family pairs, agreement was evaluated by quantifying the difference in rating within pairs for each outcome domain. The kappa statistic was not appropriate for measuring agreement within this sample because the distribution of actual responses demonstrated symmetrical unbalanced marginal totals that resulted in inappropriately low kappa scores (see online supplementary table 2), as previously described.[24] Data were analysed using SAS V.9.4 (SAS Institute, Cary, North Carolina, USA), with $p<0.05$ considered statistically significant.

RESULTS

Respondent characteristics

There were 124 patients who were eligible to participate, of whom 15 (12%) declined to complete the survey, and 31 (25%) were unable to be interviewed prior to the end of the study, leaving 78 (63%) who completed the survey. Of the 140 eligible family members, 22 (16%) declined, and 38 (27%) were unable to be interviewed prior to the end of the study period, leaving 80 (57%) who completed the survey. Within this cohort, there were 55 patient–family member pairs. On average, the interviews occurred 43 months (SD 10 months) after ICU discharge. Of the 78 survivors who responded, 38% were male, 86% were white and 29% were ≥65 years old (table 1). The 80 family member respondents had similar demographic characteristics, and 45% are spouse/partners and 21% are adult children (table 1).

Of the 265 researchers who had email addresses in their publication, three did not have working email addresses and could not be found online. Of the 262 researchers emailed, 121 (46%) responded and completed the survey. Of the 121 respondents, 67% were male, with 60% from Europe and 26% from North America (table 2). The proportions of researchers self-reporting expertise in physical, mental health and cognitive outcomes were 79%, 61% and 52%, respectively.

Patients' perspectives

Patients generally highly rated the outcome domains, with at least 80% supporting 15 of the 19 domains. The domains with the highest patient ratings (ie, >90%) were cognitive function and symptoms (96%), pain (96%), pulmonary function and

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Table 1 Characteristics of patient and family respondents

	Patient (n=78)	Family (n=80)
Male, n (%)	30 (38)	24 (30)
White race, n (%)	67 (86)	70 (89)
Age (years), n (%)		
18–24	4 (5)	2 (3)
25–44	15 (19)	12 (15)
45–64	36 (46)	41 (51)
65+	23 (29)	25 (31)
Relationship with patient, n (%)		
Partner/spouse	N/A	36 (45)
Adult child		17 (21)
Parent		16 (20)
Sibling		8 (10)
Other		3 (4)
Patient has died	N/A	11 (14)
Education in years, mean (SD)	14 (2)	14 (2)
ICU length of stay in days, mean (SD)	13 (10)	13 (10)
Months since ICU discharge, mean (SD)	43 (10)	42 (10)

Missing data: race—1 family.
ICU, intensive care unit; N/A, not applicable.

Table 2 Characteristics of researcher respondents

	n=121
Male	81 (67)
Location	
Europe (18 countries)	72 (60)
North America (two countries)	32 (26)
Australia/Oceania (two countries)	12 (10)
Asia (four countries)	5 (4)
Research and/or clinical work*	
Clinical research	108 (89)
Clinical work	71 (59)
Basic or translational research	30 (25)
Years of experience in clinical research or clinical work, mean (SD)	13 (9)
Self-reported subject expertise*	
Physical outcomes	95 (79)
Mental health outcomes	74 (61)
Cognitive outcomes	63 (52)
Clinical training†	
Physician critical care	53 (75)
Physician—other	13 (18)
Physical therapist	6 (8)
Nurse/nurse practitioner	2 (3)
Physician—physical medicine and rehabilitation	2 (3)
Psychologist	2 (3)
Respiratory therapist	2 (3)
Other	1 (1)

*Each respondent can select more than one response.
†Each respondent who has indicated any clinical work (n=71) can select more than one response.

symptoms (96%), fatigue (95%), physical function and symptoms (94%), return to work or prior activities (94%), mental health conditions and symptoms (92%) and muscle and/or nerve function (92%) (table 3; online supplementary figure 1 shows the proportion selecting 'strongly agree' for each domain).

Family members' perspectives

Similar to patients, family members highly rated the domains, with at least 80% supporting 16 of the 19 domains. The proportion of patients versus family members who supported a domain was not significantly different for 18 of the 19 domains, with the only significant difference being for the domain of swallowing function and symptoms (81% vs 94%, p=0.025; table 3; online supplementary figure 1 shows the proportion selecting 'strongly agree' for each domain). For the 55 patient–family member pairs, ≥80% of the pairs differed by no more than one response level (eg, one response level, strongly agree vs agree) for 17 of the 19 domains (see online supplementary table 3). The two domains with the lowest proportion of patient–family member pairs within one response level were sexual function and symptoms (65%) and social roles, activities or relationships (78%). Notably, when asked if they would have responded differently if the survey was asked 6 months after ICU, <4% of patients and family members said 'yes' for all domains.

Researchers' perspectives

In contrast to patients, researchers' support for measuring outcome domains in all studies was more varied, with ≥80% supporting only 6 of 19 domains. For researchers, the five most highly rated domains were survival (95%), physical function and symptoms (94%), cognitive function and symptoms (92%), return to work or prior activities (92%), and mental health and symptoms (88%) (table 3). A larger proportion of patients (vs researchers) supported all domains, except for survival (72% vs 95% supporters, p<0.001) (table 3; online supplementary figure 1 shows the proportion selecting 'strongly agree' for each domain). Four domains had high ratings by both patients and researchers: physical function and symptoms (94% vs 94%), cognitive function and symptoms (96% vs 92%), return to work or prior activities (94% vs 92%), and mental health conditions and symptoms (92% vs 88%).

Lastly, no new domains were identified after respondents were asked if there was any outcome domain missed from the 19 domains that were presented to them.

DISCUSSION

This survey of 279 participants included ARDS survivors, their family members and clinical researchers. Patients and family members, in general, rated the 19 outcome domains similarly, with the vast majority supporting to measure 18 of the 19 outcome domains in all survivorship studies. In contrast, researchers generally rated domains less strongly, with the exception of survival. Patients, family members and researchers all reported strong support for measuring the following four outcome domains in all future studies: physical function, cognitive function, return to work or prior activities and mental health.

Both patients and family members rated outcome domains related to cognition, pain, return to work/prior activities, mental health and physical outcomes (fatigue, pulmonary function, muscle/nerve function, physical function) as highly important to assess. These domains are consistent with the evaluations

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Table 3 Patient, family and researcher ratings of the importance of evaluating outcome domains in acute respiratory failure survivorship research*

Domain questions	Patients (n=78)	Family (n=80)	Researchers (n=121)	Patient vs family, p value†	Patient vs researcher, p value‡
Cognitive function and symptoms	75 (96%±4%)	80 (100%±0%)	111 (92%±5%)	0.083	0.256
Pain	75 (96%±4%)	78 (98%±3%)	101 (83%±7%)	0.623	0.006
Pulmonary function and symptoms	75 (96%±4%)	80 (100%±0%)	87 (72%±8%)	0.083	<0.001
Fatigue	74 (95%±5%)	76 (95%±5%)	92 (76%±8%)	0.958	<0.001
Physical function and symptoms	73 (94%±5%)	79 (99%±2%)	114 (94%±4%)	0.117	1.000
Return to work or prior activities	73 (94%±5%)	74 (93%±6%)	111 (92%±5%)	0.782	0.786
Mental health conditions and symptoms	72 (92%±6%)	74 (93%±6%)	106 (88%±6%)	0.962	0.350
Muscle and/or nerve function	72 (92%±6%)	79 (99%±2%)	93 (77%±8%)	0.083	0.006
Healthcare resource utilisation	70 (90%±7%)	75 (94%±5%)	84 (69%±8%)	0.387	<0.001
Type of residence	70 (90%±7%)	69 (86%±8%)	91 (75%±8%)	0.502	0.016
Impact on family and/or caregivers	69 (88%±7%)	73 (91%±6%)	84 (69%±8%)	0.547	0.002
Sleep function and symptoms	69 (88%±7%)	77 (96%±4%)	85 (70%±8%)	0.085	0.003
Satisfaction with life or personal enjoyment	68 (87%±7%)	68 (85%±8%)	92 (76%±8%)	0.695	0.067
Gastrointestinal function and symptoms	64 (82%±9%)	74 (93%±6%)	39 (32%±8%)	0.051	<0.001
Swallowing function and symptoms	63 (81%±9%)	75 (94%±5%)	58 (48%±9%)	0.025	<0.001
Financial impact on patient	58 (74%±10%)	59 (74%±10%)	61 (50%±9%)	0.748	0.001
Social roles, activities or relationships	57 (73%±10%)	58 (73%±10%)	86 (71%±8%)	0.906	0.872
Survival	56 (72%±10%)	66 (83%±8%)	115 (95%±4%)	0.106	<0.001
Sexual function and symptoms	39 (50%±11%)	36 (45%±11%)	53 (44%±9%)	0.489	0.467

*Count (% ± margin of error at 95% confidence level) of participants who selected 'agree' or 'strongly agree' on a 5-point Likert scale ranging from 'strongly agree' to 'strongly disagree'. All respondents completed rating for all 19 domains.
†p value calculated using general estimating equations with binary distribution (logistic model). For 'Cognitive function and symptoms' and 'Pulmonary function and symptoms,' the models did not converge using logistic model; hence, a Poisson model was used
‡p value calculated using Fisher's test

and impairments reported in ICU survivorship studies,[2 25 26] including in a recent systematic review of qualitative studies of ICU survivors,[27] and a recent qualitative study of posthospital patient outcomes specifically in ARF and ARDS survivors.[28] Patient–family member pairs were generally within one rating level from each other, highlighting similarity in their views. To our knowledge, no prior investigations have surveyed both ARDS survivors and family members regarding which posthospitalisation outcome domains they consider important to study. In other studies, for example, with quality of life, inter-rater agreement between patient and family has ranged from poor to excellent in different studies.[29–33] Additionally, family members are generally more accurate than clinicians at predicting patients' treatment preferences.[34 35] However, our study aimed to describe each of the stakeholder group's perspective, and we did not ask family members or researchers to respond in the way that they think the patient would have responded. The latter technique[36 37] is often used in studies that have the intent of specifically comparing inter-rater agreement, which was not the specific intent of our study.

Researchers differed from patients and their family members in the strength of their support for 12 of the 19 outcome domains. Of note, survival was the domain with the highest proportion of researchers rating 'agree' or 'strongly agree', whereas this domain received the second lowest ratings from patients. These patients may underestimate or be unaware of the high risk of mortality in the years immediately after critical illness. This difference may reflect that only surviving patients could be included in this survey. However, the number of years since their ICU discharge was not associated with the proportion of patients supporting the survival domain. Researchers may have ranked survival highly because they recognised the importance of understanding the competing risk of death when assessing all other patient outcomes in clinical research studies.[38 39] Additionally, valuing survival is consistent with previous critical care research that has traditionally used mortality as a primary outcome.[40]

After the survival domain, the four domains that garnered the next highest support from researchers were physical function, cognitive function, mental health and return to work or prior activities, which were rated similarly by patients and family members. These four domains fit within the PICS conceptual framework.[8 21 41] Furthermore, these four domains, along with survival, were highly rated by clinicians in two recent international, in-person consensus meetings that evaluated core outcome domains for ICU survivors.[22] The only outcome domain that was strongly supported in this prior research[19] that was not highly rated in the present study was health-related quality of life, which was renamed as 'satisfaction with life, or personal enjoyment' in the present study (as described in the Methods section). The change in labelling may explain this difference in results.

Gaining consensus for a common set of outcome domains that are measured in all long-term outcomes studies in ARF survivors will help advance survivorship research by reducing heterogeneity in outcomes measured[11] and decreasing bias from potential selective outcome reporting.[42 43] Moreover, findings of this study emphasise the importance of patient and family input to decision making regarding core outcome domains, which has been under-represented in prior projects aimed at creating core outcome sets.[44] Incorporating patient perspectives is important to ensure that the outcomes measured by researchers are patient centred.[45 46] Given the similarity in how ARDS survivors and their family caregivers view these outcome domains in

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the present study, including family members in the process of selecting a minimum set of outcome domains may be a feasible way to boost patient representation.

This study has several strengths including surveying a large number of patients and family members from across the USA and clinical researchers from around the world to provide a geographically diverse sample. There are also some potential limitations. First, patients and family members were interviewed at a mean (SD) of 43 (10) months after critical illness, and results may have been different at an earlier time point. However, when asked if they would respond differently if reflecting on their status at 6 months after ICU discharge, <4% responded that they would have answered differently for each of the 19 domains. Second, only approximately 50% of patients, family members and researchers responded to the survey giving rise to possible selection bias in the reported results. Additionally, there could be a potential bias related to presenting domains in a fixed order to participants. However, there were no missing data for all 19 domains for all respondents, which may help minimise this concern. Lastly, patients were exclusively ARDS survivors, enrolled in a randomised control trial and survived beyond 3 years after ARDS; hence, patients and family perspectives may not be generalisable to other ARDS cohorts, to ARF patients or to other critically ill patients.

In conclusion, patients and family members agreed that studies evaluating their outcomes after hospital discharge should measure many domains. Despite differences between patients and researchers' perspectives on the relative importance of various outcome domains, the domains with agreement across all stakeholder groups (physical function, cognitive function, return to work or prior activities and mental health) generally encompassed the existing PICS framework. Given different perspectives of patients/families and researchers, participation of both these stakeholder groups in formal consensus process is important to ensure the development of a patient-centred set of core outcome domains.

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