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Consensus statements on the utility of defining ARDS and the utility of past and current definitions of ARDS—protocol for a Delphi study

Prashant Nasa ,[1,2] Lieuwe D Bos,[1,3,4] Elisa Estenssoro,[5,6] Frank MP van Haren ,[7,8] Ary Serpa Neto,[1,9,10,11] Patricia RM Rocco,[12] Arthur S Slutsky,[13,14] Marcus J Schultz[1,15,16,17]

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For numbered affiliations see end of article.

Correspondence to
Prashant Nasa;
dr.prashantnasa@hotmail.com

ABSTRACT

Introduction Acute respiratory distress syndrome (ARDS), marked by acute hypoxemia and bilateral pulmonary infiltrates, has been defined in multiple ways since its first description. This Delphi study aims to collect global opinions on the conceptual framework of ARDS, assess the usefulness of components within current and past definitions and investigate the role of subphenotyping. The varied expertise of the panel will provide valuable insights for refining future ARDS definitions and improving clinical management.

Methods A diverse panel of 35–40 experts will be selected based on predefined criteria. Multiple choice questions (MCQs) or 7-point Likert-scale statements will be used in the iterative Delphi rounds to achieve consensus on key aspects related to the utility of definitions and subphenotyping. The Delphi rounds will be continued until a stable agreement or disagreement is achieved for all statements.

Analysis Consensus will be considered as reached when a choice in MCQs or Likert-scale statement achieved ≥80% of votes for agreement or disagreement. The stability will be checked by non-parametric χ^2 tests or Kruskal Wallis test starting from the second round of Delphi process. A p-value ≥0.05 will be used to define stability.

Ethics and dissemination The study will be conducted in full concordance with the principles of the Declaration of Helsinki and will be reported according to CREDES guidance. This study has been granted an ethical approval waiver by the NMC Healthcare Regional Research Ethics Committee, Dubai (NMCHC/CR/DXB/REC/APP/002), owing to the nature of the research. Informed consent will be obtained from all panellists before the start of the Delphi process. The study will be published in a peer-review journal with the authorship agreed as per *ICMJE* requirements.

Trial registration number NCT06159465.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This Delphi will engage a broad and diverse panel of clinical and preclinical researchers and clinicians worldwide, including those from resource-limited settings.
⇒ The Delphi process will guarantee full anonymity for the panellists and their responses, mitigating the potential for peer bias or group conformity throughout each round of the Delphi process.
⇒ The lack of a specific modalities and variations in local or regional guidelines may influence how some panellists interpret statements and form their opinions.

INTRODUCTION

Acute respiratory distress syndrome (ARDS), characterised by acute hypoxemia and bilateral pulmonary infiltrates that are not attributable to heart failure, has seen multiple definitions over the years.[1] In essence, the main objective of a formal definition is to delineate a uniform subgroup among patients within patients exhibiting a particular disease or syndrome, which may stem from various aetiologies. For an ARDS definition, this entails identifying a uniform subgroup among patients experiencing acute hypoxemic respiratory failure, which could be attributable to various critical conditions or linked with specific risk factors. This would help researchers and clinicians in prognostication, research and treatment.[2] The validity of the conceptual framework of ARDS, however, has been challenged[2] and uncertainties exist regarding the utility, or usefulness of a definition for this complication of critical illness.[3 4] Among other reasons, the lack of consensus on the conceptual model and diagnostic criteria has led to numerous revisions of the definition of ARDS.[2 5] Furthermore, there is abundant evidence of clinical and biological heterogeneity within the scope of past and current definitions.[6] This could be one of the reasons for why categorising ARDS to evaluate treatment effects has shown limited

success,[5] promoting the proposal of subphenotypes as a partial solution to this issue.[6]

The Delphi methodology has been used to generate expert consensus on components of the ARDS definition,[5 7 8] although it has not always been executed optimally. In a prior definition established in 2005, as well as in the most recent proposed definition, experts were invited based on informal recommendations from subject area experts rather than predefined criteria.[7 8] This approach may introduce bias into the results by fostering unanimity in opinion and discouraging dissent within a harmonious cohort. The 2005 definition was developed with panellists exclusively from Europe and North America.[7] While the latest definition involved a larger and more diverse panel, experts from resource-limited settings remained underrepresented. Additionally, these definitions primarily aimed at achieving consensus, overlooking other crucial considerations. One significant drawback of recent definitions was that recommendations and statements, along with their accompanying remarks or evidence, were formulated through discussions with a panel via online webinars.[5 8] This may have introduced bias due to dominance and group conformity inherent in face-to-face meetings. Even subsequent voting after online webinars is susceptible to such bias, regardless of the level of agreement.[9] In addition, the process of consensus attainment and the role of the principal investigators was not explicit. Finally, and possibly due to the aforementioned reasons, the primary objective of the latest definition—to redefine ARDS—seems to have been overlooked, resulting instead in more of an extension of previous definitions.[8]

Present here is the protocol of a forthcoming Delphi that aims to to collect global opinions on the conceptual framework of ARDS, assess the usefulness of components within current and past definitions and investigate the role of subphenotyping. This manuscript begins with an overview of the challenges associated with the conceptual framework of ARDS, examines distinctions and parallels between past and current ARDS definitions, and concludes by outlining the methods employed in the planned Delphi study.

Challenging aspects of a conceptual framework of ARDS

Clinical syndromes can be described by hypothetical constructs. Constructs are generated by similar thinking of diverse individuals to aid a shared understanding. In the absence of a gold standard, accurate diagnostic test and wide heterogeneity in its casual pathways, ARDS qualifies as a construct.[2] Indeed, clinicians use the term ARDS to describe a spectrum of conditions caused by heterogeneous aetiologies that share similar clinical and pathological characteristics.[1] The conceptual framework of ARDS described by the Berlin definition[5] includes a pathophysiology, clinical and morphological framework, which has been retained by the New Global Definition, except for minor modifications.[8]

When endeavouring to 'define' ARDS, it is important to evaluate such efforts within the framework of feasibility, reliability and validity.[10] Face validity and predictive validity have been used in previous definitions of ARDS.[5 7] While face validity is commonly assessed through surveys or expert consensus (using Delphi or nominal group methodologies), predictive validity is assessed through application of criteria in a selected cohort for comparison of prognosis or outcomes with the established standard.[2] The definition formulated in 2012 used both face validity and predictive validity;[5] however, the most recent definition was developed exclusively using face validity.[8]

Distinctions and parallels between past and current definitions of ARDS

Several definitions of ARDS have been proposed over recent decades, as summarised in table 1.[1]

In 1988, Murray *et al* introduced the first definition of ARDS, based on a lung injury score and including factors like ratio of PaO_2 to fraction of inspired oxygen (PaO_2/FiO_2), positive end-expiratory pressure (PEEP) levels, chest radiographic findings and respiratory system compliance.[11] This approach had several drawbacks, including challenges in calculating compliance in spontaneously breathing patients and the implicit assumption of equivalent scores based on different criteria. In 1994, the 'American European Consensus Conference' (AECC) definition was proposed.[12] This definition lacked an explicit timeframe for acuity and a minimum PEEP requirement for oxygenation criteria.[12] Additionally, interpreting chest radiography for bilateral infiltrates lacked reliability.[13]

In 2005, Ferguson *et al* proposed a Delphi-based definition, requiring onset within 72 hours from the insult, a minimum PEEP of 10 cm H_2O, low respiratory system compliance and exclusion of heart failure.[7] Challenges persisted with this newer definition, including the complexity of calculating compliance, but also the introduction of invasive diagnostic procedures like the use of a pulmonary artery catheter.[14] In 2012, the 'Berlin Definition of ARDS' was introduced to solve these problems.[5] This definition addressed some issues relating to the timing of onset of hypoxaemia, and also reintroduced the requirement for a minimum level of PEEP. More explicit criteria for bilateral infiltrates were formulated, and the definition was also applicable for patients receiving non-invasive ventilation. This definition has been used for many years, despite challenges with chest radiography interpretation and the need for arterial blood draws for blood gas analysis which could be impractical in settings with limited resources.[13 14]

The requirement for a minimum level of PEEP means that the diagnosis cannot be made in patients under high-flow nasal oxygen (HFNO), which is increasingly being used for respiratory support of AHRF patients, and these patients often meet the definition of ARDS once intubated and ventilated, although with a different prognosis.[15] The increased use of HFNO lead to the suggestion of allowing a diagnosis of ARDS in patients receiving HFNO with a gas flow rate of at least 30 L/min.[16] However,

Table 1 Criteria used in previous, recently proposed modifications and the recent new global definitions of ARDS

	Previous definitions				Modifications and the new global definition		
	Murray[11]	American–European consensus[12]	Ferguson[7]	Berlin definition[5]	Kigali modification[18]	Matthay[16]	New global definition[8]
Timing	Not specified	Acute onset, timing not specified	<72 hours	<1 week of a clinical insult, or new or worsening symptoms	As in Berlin	As in Berlin	<1 week of onset of predisposing risk factor, or <1 week of new or worsening respiratory symptoms
Imaging	Consolidations on CXR; 1 point for each quadrant involved	Bilateral consolidations on CXR	Bilateral consolidations involving ≥2 quadrants on CXR	Bilateral consolidations involving ≥2 quadrants on CXR or CT	Bilateral consolidations involving ≥2 quadrants on CXR, CT or bilateral B–lines on LUS	As in Berlin	Bilateral consolidations involving ≥2 quadrants on CXR, CT or bilateral B-lines on LUS
Oxygenation, PaO_2/FiO_2 (or SpO_2/FiO_2 cut-offs)*	225–299: 1 point 175–224: 2 points 100–174: 3 points <100: 4 points	≤300: 'ALI' ≤200: 'ARDS'	<200	200–300: 'mild' 100–199: 'moderate' <100: 'severe'	≤315†	As in Berlin	200–300 (or 235–315)†: 'mild' 100–199 (or 148–235)†: 'moderate' <100 (or <148)†: 'severe'
PEEP (cm H_2O)	6–8: 1 point 9–11: 2 points 12–14: 3 points ≥15: 4 points	Not specified	≥10	≥5	Not specified	≥5 in patients receiving ventilation; flow rate ≥30 L/min in patients receiving HFNO	≥5 in patients receiving ventilation; flow rate ≥30 L/min in patients receiving HFNO‡
Exclusion of heart failure or other causes	Not specified	Absence of clinical evidence of left atrial hypertension or PAOP <18 mm Hg (if measured)	Absence of clinical evidence of heart failure based on PA catheter or echocardiography	Presentation cannot be attributed solely to heart failure or fluid overload	As in Berlin	As in Berlin	Presentation cannot be attributed solely to heart failure, or fluid overload atelectasis, lung collapse, pleural effusion and pulmonary embolism
Static lung compliance (mL/cm H_2O)	60–79: 1 point 40–59: 2 points 20–39: 3 points ≤19: 4 points	Not required	<50 (under sedation, tidal volume of 8 mL/kg IBW, and PEEP ≥10 cm H_2O)	Not included	As in Berlin	As in Berlin	Not included

Continued

Table 1 Continued

	Previous definitions				Modifications and the new global definition		
	Murray[11]	American–European consensus[12]	Ferguson[7]	Berlin definition[5]	Kigali modification[18]	Matthay[16]	New global definition[8]
Risk factors	Included	Not included	Included	Not included	As in Berlin	As in Berlin	Not included
Severity	'Mild', or 'moderate to severe'*	'ALI' or 'ARDS'	Not specified	'Mild', 'moderate' or 'severe ARDS'	Not specified	As in Berlin	'Mild', 'moderate' or 'severe ARDS', or 'ARDS under HFNO'

*In 'Murray', lung injury score is calculated by the total number of points scored divided by the number of categories included (cut-offs 2.5 and 3 points).
†In the Kigali modification and the new global definition, SpO_2/FiO_2 can serve as an alternative for PaO_2/FiO_2.
‡In the new global definition, neither PEEP nor a minimum flow rate are required for a diagnosis of ARDS in resource-limited settings.
ALI, acute lung injury; ARDS, acute respiratory distress syndrome; CXR, chest radiography; FiO_2, fraction of inspired oxygen; HFNO, high-flow nasal oxygen; IBW, ideal body weight; LUS, lung ultrasound; PaO_2, partial arterial pressure of oxygen; PA(OP), pulmonary artery (occlusion pressure); PEEP, positive end-expiratory pressure; SpO_2, peripheral capillary oxygen saturation.

patients receiving HFNO who fulfilled the non-PEEP ARDS criteria, and ARDS patients receiving ventilation had distinct baseline characteristics and also different mortality rates.[17]

The last two definitions, the 'Kigali Modification of the Berlin Definition'[18] and the 'New Global Definition of ARDS'[8] addressed this last concern by allowing the use of the ratio of SpO_2 to fraction of inspired oxygen (SpO_2/FiO_2) and also allowing the use of the definition in patients that remained non-ventilated. Main concerns about these last two definitions include the facts that specificity could become low, and also limitations with regard to the usefulness of SpO_2 in certain conditions.[19]

Categorisation of ARDS

Clinical, biological and physiological heterogeneity among patients with ARDS drives differential treatment effects, which may explain the clinical trial failures of various interventions tested in unselected patients with ARDS. Recent guidelines on the management of ARDS describe the potential for precision-based treatments based on subphenotypes.[20] There are various attempts to categorise ARDS based on aetiological, physiological, radiological and biological criteria to evaluate heterogeneity of treatment effect, for prognostication, or for identification of targeted-therapies (figure 1).[21] Subgroups, phenotypes, subphenotypes and endotypes have been described using these features (table 2).[6] However, we only aim to test the utility of subgroups and subphenotypes of ARDS, for this study.

Physiology-based categorisation

Physiology-based categorisation of ARDS has evolved from the 'AECC' definition to the 'Berlin Definition of ARDS', with classifications based on PaO_2/FiO_2 ratios.[12] However, the interpretation of terms like 'acute lung injury' (ALI) led to confusion among clinicians. Subgroups based on these ratios are somewhat arbitrary,[6] with varying thresholds used in research studies.[22–25] While other physiological variables like driving pressure and mechanical power show promise in predicting ARDS outcomes, evidence on interventions targeting these variables is lacking.[6] Ventilator settings, for example, the level of PEEP or FiO_2 can influence these physiological parameters, potentially altering the severity classification of ARDS. Therefore, recommending treatments based solely on PaO_2/FiO_2 cut-offs may not be appropriate.[26 27] Dead space calculation methods and ventilatory ratio show associations with mortality, but targeted therapies require validation in clinical trials.[28]

Radiology-based categorisation

Radiology-based categorisation distinguishes focal and non-focal ARDS based on chest CT scans. Personalised ventilation strategies have been explored, but misclassification poses challenges.[29] Routine chest X-rays can quantify lung oedema using the Radiographic Assessment of Lung Edema (RALE) score, which correlates with

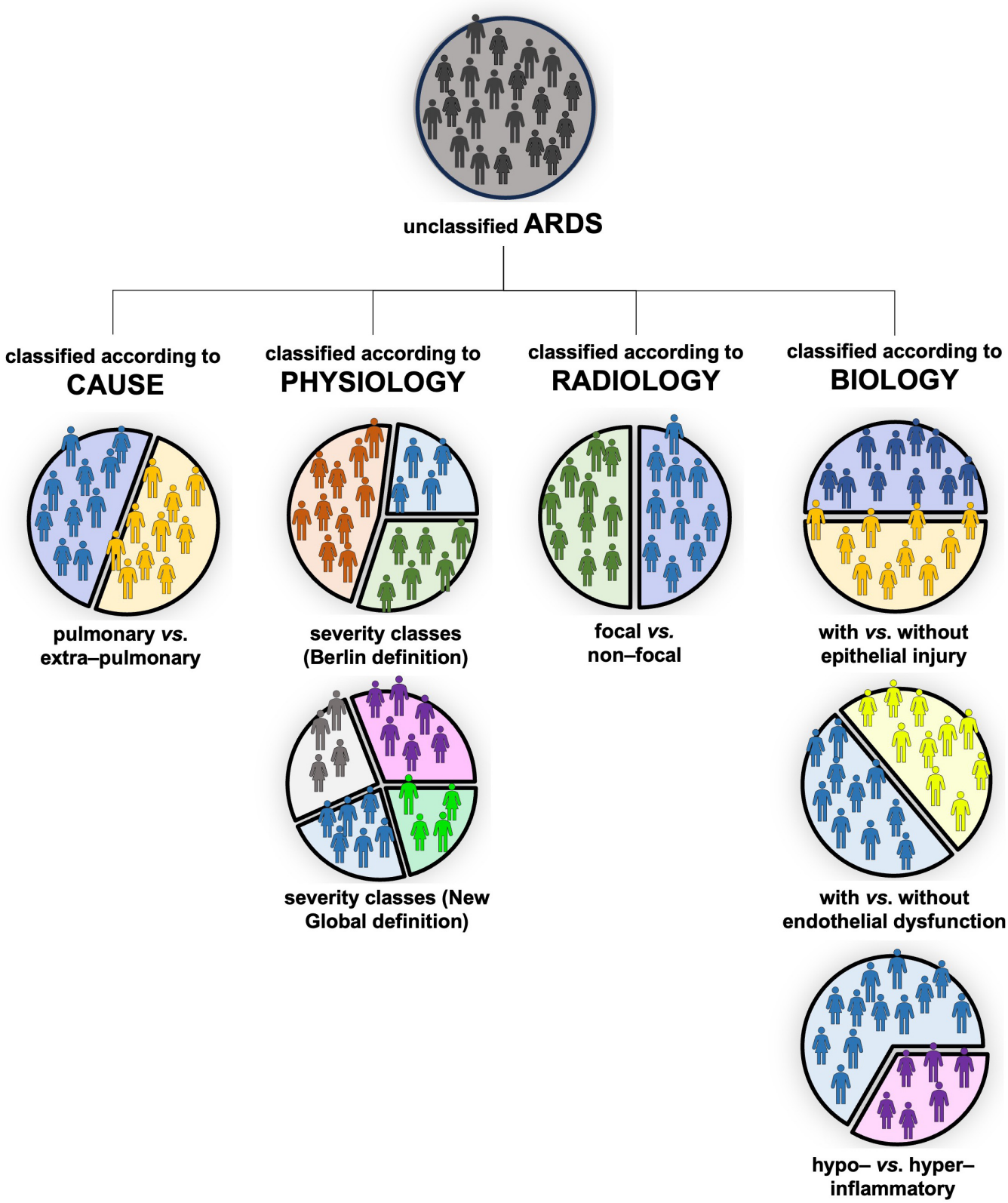

Figure 1 Subgroup, phenotypes and subphenotypes proposed for acute respiratory distress syndrome. Of note, (1) pulmonary vs extrapulmonary is sometimes called direct vs indirect in the literature; (2) physiological assessment can be based on continuous data (PaO_2/FiO_2 or SpO_2/FiO_2), which are then dichotomised arbitrarily to create severity classes; (3) patients with non-focal ARDS more frequently have extrapulmonary ARDS and more frequently have severe ARDS; (4) epithelial injury and endothelial dysfunction are not mutually exclusive and (5) most patients with hyperinflammatory ARDS have extrapulmonary ARDS, more frequently have severe ARDS and almost always have non-focal ARDS. ARDS, acute respiratory distress syndrome; PaO_2/FiO_2, partial pressure of oxygen to fraction of inspired oxygen; SpO_2/FiO_2, peripheral capillary oxygen saturation to a fraction of inspired oxygen.

Table 2 Nomenclature used for (sub)phenotyping of ARDS[6]

	Definition	Classification of a patient
Phenotype	Clinically observable set of traits resulting from an interaction of genotype and environmental exposures	ARDS
Subgroup	Subset of patients within a phenotype, defined using any cut-off in any variable. The cut-off can be arbitrary and patients and frequently patients fall just on either side of it resulting in patients switching subgroups	Severity classification based on oxygenation criteria (PaO_2/FiO_2)
Subphenotype	Distinct subgroups that can be reliably discriminated from other subgroups based on a set or pattern of observable or measurable properties. Discrimination is data-driven assessment of a multidimensional description of traits. Subphenotypes are reproducible in different population	Hypoinflammatory or hyperinflammatory subphenotype
Endotype	Subphenotype with distinct functional or pathobiological mechanism, which preferably responds differently to a targeted therapy	Unknown

ARDS, acute respiratory distress syndrome; PaO_2/FiO_2, partial pressure of oxygen to fraction of inspired oxygen

outcomes, but evidence on its concordance with CT scans and treatment efficacy is limited.[30 31] Lung ultrasound offers a non-invasive imaging option but interobserver variation, challenges in procuring images in certain settings (eg, obesity and subcutaneous emphysema) and the inability to detect lung hyperinflation are a few of its limitations.[32] ARDS subphenotypes, including recruitable and non-recruitable categories, have been identified using physiological and imaging data. These subphenotypes show differences in response to interventions and mortality rates, with similar findings observed in COVID-19-related ARDS.[33 34]

Biological-based categorisation

Biological-based categorisation using biomarkers like interleukins can differentiate hyperinflammatory from hypoinflammatory ARDS, influencing treatment responses and outcomes.[35 36] However, challenges in bedside availability of biomarkers persist. These subphenotypes remain subjects of ongoing research, with uncertain implications for clinical management and prognostication. Patients may transit between subphenotypes during their illness.[26 37] Large randomised studies are needed to validate the utility of subphenotyping in ARDS management.[20]

METHODS

Design

The Delphi methodology will be used in this study to generate consensus (or dissensus). A Steering Committee comprised of physicians and researchers with experience in the management of AHRF or ARDS in critically ill patients has been formed (see list of authors of this paper). This Steering Committee will identify and select 'Panellists' from across the globe based on predefined criteria. In order to reach an agreement among the panellists, the Steering Committee members will conduct iterative Delphi rounds after conducting a literature search on the currently available evidence and drafting the opening statements.[9 38] The members of the Steering Committee will not be respondents to the Delphi surveys. The study has been granted waiver for ethical approval due to nature of the study from the NMC Healthcare Regional Research Ethics Committee, Dubai (NMCHC/CR/DXB/REC/APP/002). An updated and finalised analysis plan will be uploaded at the end of the Delphi.

Objectives

The Delphi process has four objectives:

1. To review the value of having a definition of ARDS, with a focus on its purpose for research, education, and patient management.
2. To review the utility of various elements in past and current definitions of ARDS, including but not limited to the utility of subgroups of ARDS.
3. To review the utility of subphenotyping of ARDS, with a focus on its purpose for research, education, prognostication, and patient management.
4. To generate consensus on research priorities regarding definitions of ARDS and subphenotyping based on the criteria used for subphenotyping of ARDS (table 2).

Panel

A diverse panel of 35–40 panellists from different professional disciplines, such as Internal Medicine, Intensive Care Medicine, Respiratory Medicine, Anaesthesiology and Physiology, with experience in the field of ARDS will be selected based on the following criteria:

1. At least 5 years of clinical experience as a staff member, with care for AHRF or ARDS patients or preclinical expertise (of more than 5 years) in AHRF or ARDS.
2. At least five publications (original studies) as a leading or senior author or member of the steering committee of an observational study or a randomised controlled trial (RCT) in AHRF or ARDS.
3. Not more than 70% of the panellists from each sex; and from each of high and low-middle-income countries.

4. Not more than 25% of panellists from the previous or current definitions of ARDS (including the Berlin Definition of ARDS, the Kigali Modification of the Definition of ARDS and the New Global Definition of ARDS).

Purposive sampling will be used to recruit the panellists after screening through recent publications in the field of AHRF. Panellists will be selected based on the predefined selection criteria and concerted efforts to attain a balance of sex and geographical location. The panellist will be invited through e-mail, explaining their role, the objectives of the study and the Delphi process. The panellists who accepted the invite will be engaged in the Delphi process, and active efforts will be made to retain them through periodical communication on the study status. The study status will be communicated in the Delphi round reports and after each round. To prevent the dropout of the panellist from the Delphi process, at least three e-mails will be sent during each round and any concerns/feedback related to the process will be addressed. Further, a schedule of Delphi rounds (each over 2 weeks) will be followed for the Delphi rounds to ensure the continuity of the process.

The consensus (Delphi) process

Step 1: establishing a preliminary list of broad domains

A literature review on the definitions and phenotypes of ARDS will be performed by the Steering Committee members. The available evidence (or lack thereof) will be used to draft statements under four broad domains for round 1 of the Delphi process.

Domains

1. Conceptual model of ARDS.
2. Usefulness of definition of ARDS and its components.
3. Utility of subphenotyping of ARDS.
4. Future research

Step 2: preparation of the Delphi round 1 survey

The experts will receive a Delphi questionnaire on Google Forms with a list of questions pertaining to the aforementioned domains. During the Delphi rounds, the panellists and their responses will be anonymised. The panellists will be asked to respond to the questionnaire based on their expertise and understanding of the subject. Multiple-choice questions (MCQs) and a 7-point Likert scale will be used in the questionnaire. The original statements for round 1 Delphi survey are provided in the online supplement. The responses and comments of panellists will be compiled through a report and provided as controlled feedback in the subsequent survey.

Step 3: subsequent Delphi rounds

The Steering Committee will review the results of the round through virtual meetings. Based on the feedback, comments and responses received, the statements will be modified, deleted or added. The remaining statements will be continued in the subsequent rounds until a stable consensus (or dissensus) is achieved (≥80% voting on agreement (disagreement) on Likert-scale and option(s) in an MCQ). The summary results of each round will be presented to panellists, and the survey process will be repeated with the modified questionnaire. Statements will be continued in the Delphi rounds until stability of the response is achieved, and there are no comments requiring adjustment from more than 10% of the panellists. The Delphi process will continue until the stability is achieved for all statements.

Step 4: final consensus

The summary results of the last stable Round will be utilised to draft position statements.

Patient and public involvement

The involvement of patients and the public in this study has been omitted. Given the complexity of the inquiries and statements, as well as the difficulties in integrating patient perspective into the technical aspect of defining, categorising, and subphenotyping of ARDS, the steering committee decided to exclude patient and the public from participating in the study.

Analysis plan

A descriptive analysis of each survey will be performed. For the Delphi process, stability will be checked by non-parametric χ^2 tests or Kruskal Wallis test from round 2 onwards. A p-value ≥0.05 will be used to define stability (or no significant variation).

Consensus will be considered as reached when a choice in MCQs or Likert-scale statement achieved ≥80% of votes.[9] We opted for a threshold of 80% for consensus, as used in few recent Delphi studies in the domain of intensive care medicine.[39–41] A statement will be continued in the Delphi round until the stability of the response is achieved. Consensus (or dissensus) statements will be considered as those that generate both consensus (or dissensus) and stability.

Reports of the Delphi rounds will be prepared by the steering committee and shared with the panel, along with the Delphi questionnaire of the subsequent round. The report will present the overall consensus (or dissensus) on each statement, along with the stability of the responses. Final results will be prepared with a percentage of voting for each option of MCQs, or the percentage of votes on agreement, neutral and disagreement in the Likert-scale statement. The final survey results, position statements and the article will be circulated among Panellists before publishing.

DISCUSSION

Delphi methodology is a valuable and pragmatic tool for constructing definitions based on expert opinions. Indeed, while RCTs are designed to rigorously assess the efficacy of interventions or treatments by randomly assigning participants to different groups, allowing researchers to draw conclusions about cause-and-effect

relationships. They provide high-quality evidence that informs clinical practice and healthcare decision-making. In contrast, Delphi studies aim to generate consensus among experts on complex issues where evidence might be limited or conflicting. Through iterative rounds of feedback, Delphi studies gather opinions from a panel of experts, helping to synthesise knowledge and identify areas of agreement or contention. While RCTs are pivotal for establishing evidence-based guidelines and protocols, Delphi studies offer valuable insights of expert participants on a particular subject. Finally, for the definition of a construct, a Delphi approach is preferred to capture the agreement on the gestalt.[2]

Through the current Delphi, we attempt to assess the usefulness of the conceptual model of ARDS and the utility of ARDS definitions through a collective opinion of panellists, with a focus on its purpose for research, education and patient management. The panel will also opine on the utility of subphenotyping of ARDS, with a focus on its purpose for research, education and clinical care including prognostication and patient management, and generate consensus on research priorities regarding definitions of ARDS and subphenotyping and the criteria used herein.

The conceptual model of ARDS, a reflection of its pathophysiology, has been the basis for all definitions of ARDS to date. The model includes risk factors, pathology findings, clinical presentation and evolution in response to clinical management. However, agreement on the need for individual components must still be improved.[5 8] Through our Delphi study, we will evaluate the agreement on various characteristics of the conceptual model. This will generate collective unbiased opinions from a wide panel of global clinical and preclinical researchers and clinicians on the usefulness of the ARDS definition and its various components in characterising the conceptual model.

The study also intends to generate consensus on the utility of various elements and their potential role in defining and categorising ARDS in the context of education, research and bedside clinical management. Consensus will also be generated for the utility of categorisation of ARDS and directions for future research in ARDS.

Delphi methodology remains a valuable and pragmatic tool for constructing definitions based on expert opinions. Moreover, practitioners often modify the Delphi technique to ease the decision-making and consensus, undermining its quality and credibility.[38] Recently, experts recommended certain standards for the design, conduct and reporting of Delphi studies for an unbiased and credible opinion.[42] The design and execution of a Delphi study should encompass systematic research into existing evidence, establish predefined criteria for expert panel selection, define consensus criteria and statement handling procedures in advance, detail the explicit iterative process, ensure response anonymity and assess the stability of consensus (or its absence). The selection process of the experts, the methodology for reaching consensus, response rates and a discussion of any methodological limitations will be reported in the results.

ETHICS AND DISSEMINATION

The study will be conducted in full concordance with the principles of the Declaration of Helsinki and will be reported according to CREDES guidance. This study has been granted an ethical approval waiver by the NMC Healthcare Regional Research Ethics Committee, Dubai (NMCHC/CR/DXB/REC/APP/002), owing to the nature of the research. The key ethical considerations of the study are peer pressure and group biases. To mitigate this, the experts will remain anonymous to each other till the end of the Delphi process. Informed consent will be obtained from all panellists before the start of the Delphi process. The study will be published in a peer-review journal with the authorship agreed as per *ICMJE* requirements.

Study progress to date

The Delphi process of the study is completed on 31 March 2024 and currently the Steering Committee is analysing the results and will be drafting the postion statments and the manuscript.

Author affiliations
[1]Department of Intensive Care, Amsterdam UMC, Amsterdam, The Netherlands
[2]Department of Critical Care Medicine, NMC Specialty Hospital, Dubai, UAE
[3]Laboratory of Experimental Intensive Care and Anesthesiology, Amsterdam UMC, Amsterdam, The Netherlands
[4]Department of Respiratory Medicine, Amsterdam UMC, Amsterdam, Netherlands
[5]Facultad de Ciencias Médicas, Universidad Nacional de la Plata, La Plata, Argentina
[6]Ministerio de Salud de la Provincia de Buenos Aires, La Plata, Argentina
[7]College of Health and Medicine, Australian National University, Canberra, ACT, Australia
[8]Intensive Care Unit, St George Hospital, Sydney, NSW, Australia
[9]Monash University, Clayton, VIC, Australia
[10]Austin Hospital, Heidelberg, VIC, Australia
[11]Hospital Israelita Albert Einstein, São Paulo, Brazil
[12]Laboratory of Pulmonary Investigations, Carlos Chagas Filho Institute of Biophysics, Federal University of Rio de Janeiro, Rio de Janeiro, Brazil
[13]Interdepartmental Division of Critical Care Medicine, University of Toronto, Toronto, Ontario, Canada
[14]St Michael's Hospital Li Ka Shing Knowledge Institute, Toronto, Ontario, Canada
[15]Mahidol Oxford Tropical Medicine Research Unit, Bangkok, Thailand
[16]Nuffield Department of Medicine, Oxford University, Oxford, UK
[17]Department of Anaesthesiology, General Intensive Care and Pain Medicine, Division of Cardiac Thoracic Vascular Anesthesia and Intensive Care Medicine, Medical University Vienna, Vienna, Austria

X Ary Serpa Neto @a_serpaneto

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ORCID iDs
Prashant Nasa http://orcid.org/0000-0003-1948-4060
Frank MP van Haren http://orcid.org/0000-0001-8037-4229

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