

Online Supplemental Material

Title: Potentially modifiable factors contributing to outcome from Acute Respiratory Distress Syndrome: the LUNG SAFE study

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APPENDIX 3 – LUNG SAFE Protocol and Case Report Form

3.1 LUNG SAFE Study Protocol

Large observational study to Understand the Global impact of Severe Acute respiratory Failure (LUNG-SAFE) Study

Protocol Version – December 9, 2013

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INTRODUCTION

The original description of Acute Respiratory Distress Syndrome (ARDS) dates back more than 40 years. After the landmark definition provided by the American European Consensus Conference in 1994 [1], the definition was recently updated, by the “ARDS definition task force” (an initiative of the European Society of Intensive Care Medicine endorsed by the American Thoracic Society and the Society of Critical Care Medicine) which proposed and validated the “Berlin definition”[2], with the aim of overcoming some of the limitations which have emerged in regard to the 1994 definition.

Several large observational population studies have been conducted in the last 10 years, with the aim of describing the ICU incidence and outcome of ARDS patients as well as collecting clinical and physiological variables, with a specific focus on mechanical ventilator settings [3-5]. These studies have provided great insights into the understanding of ARDS: far from the carefully controlled settings of randomized controlled trials these studies provide a “real-life

picture” of ARDS patients and of clinicians’ response.

However, important advances and changes in the management of patients with respiratory failure have occurred. First, the use of non-invasive ventilation to delay/prevent intubation has rapidly increased. The 1994 definition of ARDS required the patient to be supported by mechanical ventilation. Second, protective ventilation has become more established and the use of adjuncts such as ECMO has increased substantially in the last five years. Third, the patient population is also changing, as elderly patients are more commonly admitted into ICUs. Perhaps most importantly, the definition of ARDS itself has recently changed.

For these reasons the Acute Respiratory Failure section of ESICM proposes to undertake the “LUNG SAFE study”, in order to prospectively assess the incidence of, and outcomes from ARDS, as defined by the Berlin definition.

In summary, the study will focus on the following items:

- The frequency and disease burden of acute hypoxaemic respiratory failure in winter
- The aetiologies of acute hypoxaemic respiratory failure requiring ventilatory support.
- The incidence of ARDS based on the Berlin definition within this patient cohort
- The mortality from ARDS within this cohort, and how does this vary based on ARDS severity
- Natural history of ARDS (duration and evolution by severity)
- Therapeutic resource utilization
 - Use of treatments, such as recruitment maneuvers, prone positioning, nitric oxide, high frequency oscillation, ECMO, transfer to tertiary hospital from smaller regional ones) according to the severity of the disease
 - Use of non-invasive ventilation in management of ARDS patients (use in different stages: early ARDS versus immediately after extubation)

METHODS

This is a prospective observational study, aimed at collecting an adequate dataset on a large cohort of patients admitted to a large number of ICUs.

ICU RECRUITMENT AND PARTICIPATION

ICUs will be invited to participate on a voluntary basis. ICUs enrolling into existing databases (e.g., ERIC study, ICON audit) will be invited to participate. It is important that participating ICUs commit (by written agreement) to fully comply with the study protocol.

ICU recruitment in each country will be spearheaded by a national coordinator. Each ICU will be requested to recruit for **4 consecutive ‘winter’ weeks**

- Northern Hemisphere – 4 week period between February 1st and March 31st 2014.
- Southern Hemisphere: 4 week period between June 1st – August 31st 2014

There will be 2 data collectors per participating ICU’s. Each data collector will undergo an online training program designed to standardize data interpretation [esp. CXR’s] and will receive a login authorization following completion of this training.

INCLUSION CRITERIA: All patients admitted to the participating ICUs receiving invasive or non- invasive ventilation will be screened and included in the database.

EXCLUSION CRITERIA: Age < 16

DATA COLLECTION

Data collection will be web based, permitting conditional Data Collection screens, i.e. data collectors will be automatically guided as to which sections to complete based on data entered indicating whether Inclusion Criteria are met. Data collection will be done at 10am each morning.

Form #1: This is completed by each participating ICU just prior to study commencement. It will provide a set of data concerning its own size, staff, case-mix.

Form #2: Completed at ICU admission on all patients in participating ICUs

Form #3: Completed on all patients receiving: (1) CPAP > 5cm H₂O, or Assisted ventilation (invasive or non-invasive) with PEEP CPAP > 5cm H₂O and with a P/F ratio <300 [<40 if PO₂ in KPa]. Patients will be reassessed daily and if they fulfill inclusion criteria will have form #3 completed at that point, and be entered into the study at that point. Day 1 is the date of fulfillment of the inclusion criteria. Data will be collected daily for Study Days 1-7 inclusive, then on Study Days 10, 14, 28, and at ICU death or discharge. **Forms #4 and 5:** Completed at ICU and at either hospital discharge or day 90 [whichever comes first] respectively.

SAMPLE SIZE

Our aim is to obtain a sample of at least 1000 ARDS patients within the cohort of patients receiving assisted ventilation. The reported incidence of ARDS in ICU patients varies, from 2.2% of ICU admissions develop ARDS in ALIEN [3], 7.1% in ALIVE Study [6], to 17.5% of Ventilated patients in KCLIP [7]. A reasonable projection of the incidence of ARDS among patients admitted in ICUs can be estimated to approximate 5% of ICU admission. As a conservative estimate, if a medium-sized ICU admits 50 patients/month and collects data for four weeks, 500 ICUs will be necessary to achieve this number.

ETHICAL APPROVAL AND PATIENT'S CONSENT

We believe that informed patient consent will not be necessary, as this audit is purely observational, the data collected are part of routine clinical care, and the data will be anonymized. However, each PI will notify the relevant ethics committee, in compliance with the local legislation and rules. The national coordinators will facilitate this process.

DATA ANONYMIZATION AND DE-IDENTIFICATION

The study will not store electronically any data which allow direct patient's identification (such as name and/or date of birth). Only initials and age are collected and the patient is then assigned a unique identifier number, generated by the eCRF, used to identify the data, but investigators are allowed not to enter patient's initials in the eCRF. Upon enrollment in the eCRF, the patient is assigned a unique identifier number, termed the Study ID, which is used subsequently to identify the data. If initials are not inserted in the eCRF a record connecting patient's initials and Study ID can be retained locally, to facilitate data collection. At the end of the study, a verification of all data in the database is carried out, and the local site coordinator asked to verify specific data as needed. Once this is done, the database is locked and before the beginning of the statistical analysis the patients' initials will be erased from the dataset. The individual site coordinators are then asked to destroy all identifying information, including the record linking

the patient's initials to their Study ID. Thereafter, data will only be identified with the unique Study ID. The data is stored securely and all procedures regarding data management will comply with EU directive on data protection 95/46/EC. Further details can be found in the document signed by Clinfile, provider of the electronic CRF.

After study completion the database will be securely stored to avoid accidental or unauthorized disclosure or access. Access to the database will be granted to the "Lung Safe" investigators only, to perform the statistical analysis described in the attached plan. Lung safe investigators have the right to propose additional analysis of the collected data, subject to approval of the Principal investigators.

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3.2. Case Report Form (Paper Version)

DAILY SCREENING FORM

Patient’s initials: _____ Date of admission: _____ Time of admission: _____ Gender: M F

Year of Birth: _____ Type of admission: Medical/Surgical/Postoperative (elective)

Days since admission	Date	Mechanical ventilation (circle the appropriate mode)	Lung fields on Radiology	PaO2	FiO2	PaO2/FiO2	Severe respiratory failure Criteria fulfilled
0		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
1		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
2		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
3		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
4		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
5		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
6		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
7		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
8		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
9		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
10		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
11		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
12		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO

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		None of the Above	Not done				
13		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
14		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
15		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
16		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
17		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
18		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
19		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
20		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
21		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
22		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
23		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
24		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
25		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
26		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO
27		Inv. MV PEEP≥5/ NIMV EPAP≥5/ CPAP≥5/ None of the Above	Normal/ Abnormal/ Not done				<input type="checkbox"/> YES <input type="checkbox"/> NO

***If NIV/IV/CPAP with end expiratory pressure >5 cmH₂O AND abnormal lung radiology AND PaO₂/FiO₂<300 mmhg (or < 40kPa), please move to the "Study form", otherwise, please reevaluate the patient the next day**

BASELINE DATA COLLECTION FORM - Study Day 1

Date of fulfillment of criteria for severe respiratory failure (from screening form): _____

Date of Hospital Admission: __ / __ / 201__ __: __ (24 h clock)

Height (first documented at ICU admission): _____ inch cm

Weight (first documented at ICU admission): _____ lbs kg

Admission Source:

- Other hospital (ICU) Other hospital (Ward) ER/ambulance
 Operating Room Study Hospital (Ward) Study Hospital (Other ICU) Other, please specify _____

If patient transferred from another hospital and/or ICU:

What was date of Admission to that Hospital: _____

If patient transferred from external ICU, what was date of ICU Admission: _____

Reason for transfer: ICU Bed Unavailability Need for more advanced support

Need for specialty medical input Other (please be precise): _____

Co-morbidities (check all that Apply):

- COPD
 Diabetes Mellitus
 Chronic Renal Failure
 Active Neoplasm
 Hematologic neoplasm
 Immunosuppression
 Heart failure: NYHA classes III-IV
 Chronic liver failure (Child-Pugh Class C)
 Home Ventilation

ARDS Risk Factor (check all that apply):

Direct	Indirect
Pneumonia	Non-pulmonary sepsis
Aspiration of gastric contents	Major trauma
Inhalational injury	Pancreatitis
Pulmonary contusion	Severe burns

	Pulmonary vasculitis		Non-cardiogenic shock
	Drowning		Drug overdose
			Multiple transfusions/transfusion-associated acute lung injury (TRALI)
	OTHER (Specify):		
	NONE		

Date of the insult: __ / __ / ____ OR Not Known

Can hypoxemia be entirely explained by cardiac failure?

Yes No

**Did you use any of these method to rule out the cardiac origin of the disease?
(check all that apply):**

	Echocardiography
	Pulmonary artery catheter
	Transpulmonary thermodilution (e.g., PiCCO)
	Other (specify):
	None:

**What is/are the cause(s) of the patient’s acute hypoxemic respiratory failure
(check all that apply)?**

- Pneumonia
- Cardiac Failure
- Asthma
- ARDS
- COPD
- Unknown
- Other _____

Are there new or worsening respiratory symptoms within the last week?

Yes No

DAILY DATA COLLECTION FOR PATIENTS WITH SEVERE RESPIRATORY FAILURE¹

Day _____ Date of this form _____

Is the patient in the ICU on this date? YES NO*

* If “NO” please complete the discharge/Death forms

ARTERIAL BLOOD GAS	Units	Value
pH:		
PaO ₂ :		
PaCO ₂ :		
FiO ₂ :		
Arterial blood gas not available		<input type="checkbox"/>
SpO ₂		

CHEST X-RAY (CXR) / CT SCAN	
Chest x-ray (CXR) / CT scan not available	<input type="checkbox"/>
Bilateral opacities on the CXR/CT scan	Yes <input type="checkbox"/> No <input type="checkbox"/>
Number of involved quadrants:	1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/>

Mechanical Ventilation (Please record ventilatory settings as close as possible to the ABG):

Invasive Non-invasive Only O₂ None

Modality

- Volume A/C
- PC/BIPAP/APRV
- SIMV
- PRVC
- PSV
- NAVA
- HFO
- CPAP
- T-Tube
- Other

¹ Data is collected at at 10am on Days 1,2,3,5,7 inclusive, Day 10, 14, 21, 28 until ICU discharge/death.

Ventilatory settings:	
Respiratory Rate (set)	
Respiratory Rate (Total)	
Tidal Volume (ml)	
PEEP (cmH ₂ O)	
Plateau Pressure available?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Plateau Pressure (cmH ₂ O)	
Peak Inspiratory Pressure (PIP) (cmH ₂ O)	
Mean Airway Pressure (MAP) (cmH ₂ O)	
Is the patient triggering the Ventilator?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Oxygen flow (for t-tube or O ₂ therapy)	

Adjunctive Measures/Therapies (in the last 24 hours – check all that apply)

Prone positioning *	CT scan
Recruitment maneuvers	Alveolar surfactant
Extracorporeal membrane oxygenation (If yes: V-V or A-V or V-A)	Lung Ultrasound
High dose corticosteroids	Renal Replacement Therapy
Almitrine besylate	Tracheostomy
Continuous Sedation	Inhaled vasodilators
Oesophageal pressure monitoring**	Neutrophil Elastase Therapy
Continuous Neuromuscular Blocking Agents	
Pulmonary Artery Catheter	Mean pulmonary arterial pressure: _____
None of the above	

Sequential Organ Failure Assessment (SOFA) Score (worst value over last 24hrs)

SOFA Score	Units	Value	NOT AVAILABLE
Estimated Glasgow Coma Scale			<input type="checkbox"/>
Mean Arterial Pressure	mmHg		<input type="checkbox"/>
Vasopressors used? Yes/No			
Dopamine infusion			<input type="checkbox"/>
Dobutamine infusion			<input type="checkbox"/>
Noradrenaline infusion			<input type="checkbox"/>
Adrenaline infusion			<input type="checkbox"/>
Platelet Count($\times 10^3/\text{mm}^3$)			<input type="checkbox"/>
Total Bilirubin	$\mu\text{mol/L}$ mg/dL		<input type="checkbox"/>
Creatinine (mg/dL)			<input type="checkbox"/>
OR Creatinine ($\mu\text{mol/L}$)			<input type="checkbox"/>
OR Urine Output (mL/day)			<input type="checkbox"/>

*** For Patients Receiving prone position:**

	Units	Supine (before pronation)	Prone
pH:	-----		
PaO ₂ :			
PaCO ₂ :			
PEEP	cmH ₂ O		
Plateau pressure	cmH ₂ O	<input type="checkbox"/>	
Duration of the session	hours		

**** For Patients receiving Oesophageal pressure measurement:**

Why was esophageal pressure used?

- To measure chest wall elastance
- To facilitate PEEP titration
- To assess the Work of breathing
- To assess synchrony
- Other: _____

OUTCOME AND ICU DISCHARGE/DEATH

OUTCOMES AT ICU DISCHARGE/DEATH

<p>ICU (or day 90) Outcome (whichever event comes first)</p> <p><input type="checkbox"/> Alive <input type="checkbox"/> Dead</p> <p>Date of ICU discharge/Death: __ / __ / ____</p> <p><i>For patients without severe respiratory failure only this section is necessary</i></p>

Discharged to:

- Other ICU Hospital Ward Intermediate Care Unit Hospital Discharge

Did the patient develop additional risk factors for ARDS (in addition to those indicated in the "STUDY DATA-BASELINE" form) (check all that apply):

Direct	Indirect
Pneumonia	Non-pulmonary sepsis
Aspiration of gastric contents	Major trauma
Inhalational injury	Pancreatitis
Pulmonary contusion	Severe burns
Pulmonary vasculitis	Non-cardiogenic shock
Drowning	Drug overdose
	Multiple transfusions/transfusion-associated acute lung injury (TRALI)
OTHER (Specify):	

Could patient hypoxemia be entirely explained by cardiac failure?

- Yes No

Did you use any of these method to rule out the cardiac origin of the disease? (check all that apply):

<input type="checkbox"/>	Echocardiography
<input type="checkbox"/>	Pulmonary artery catheter
<input type="checkbox"/>	Transpulmonary thermodilution (e.g., PiCCO)
<input type="checkbox"/>	Other (specify):
<input type="checkbox"/>	None:

Did the patient have ARDS at any stage of their ICU stay?

- Yes No

Respiratory status at ICU Discharge (Check all that apply):

- Tracheostomy Invasive ventilation Non-invasive ventilation CPAP
 Oxygen therapy No oxygen therapy

Date of liberation from MV: __ / __ / ____

If patient did not survive:

What was the most important factor leading to ICU Death (Check one)?

- Respiratory Failure
- Cardiovascular Failure [i.e. Unresponsive Shock]
- Renal Failure
- Hepatic Failure
- Coagulation Failure
- Neurologic Failure

Limitations in Care

Was there a decision to withhold a life sustaining measure at any time during the ICU stay? Yes No

Was there a decision to withdraw a life sustaining measure at any time during the ICU stay? Yes No

Date of decision to withhold/withdraw life sustaining measures: __ / __ / ____

Did the patient undergo an autopsy (i.e. post mortem) examination

- Yes No

If an Autopsy was performed, what did lung histology demonstrate [Check all that apply]

- Pneumonia
- Diffuse Alveolar Damage
- Pulmonary Oedema
- Atelectasis
- Alveolar Haemorrhage
- No lung pathology
- Other (Specify) _____

DISCHARGE/DEATH

ADDITIONAL DISCHARGE FORM FOR PATIENT WITHOUT RISK FACTORS FOR ARDS

This form is required only for patients with “none” selected as risk factor for ARDS

Was a broncho-alveolar lavage (BAL) fluid analysis performed? Yes No

If yes, please provide

○ Day BAL performed*: __ / __ / _____

○ Cytological analysis:

Macroscopic aspect: normal bloody or pink lactescent

Number of cells: _____ / mL

Macrophages: __ % lymphocytes: __ % neutrophils: __ %

mast cells: __ % eosinophils: __ % siderophages: __ % other cells: __ %

○ Microbiological analyses performed (check all that apply):

Bacterial culture

Pneumocystis jiroveci stain or PCR

Fungal analysis

Viral PCRs

Positive result(s): _____

*if several BAL were performed: results of the nearest to the ARDS diagnosis

Were immunological tests performed?

Yes No

If yes, please check if the result is positive:

antinuclear antibodies

Antisynthetase antibodies

Anti-CCP antibody

ANCA

Rheumatoid factor

Other: _____

DISCHARGE/DEATH

HOSPITAL OUTCOME

Hospital (or 90 day) Outcome (whichever event occurs first)

Alive Dead

Date of hospital discharge: __ / __ / ____