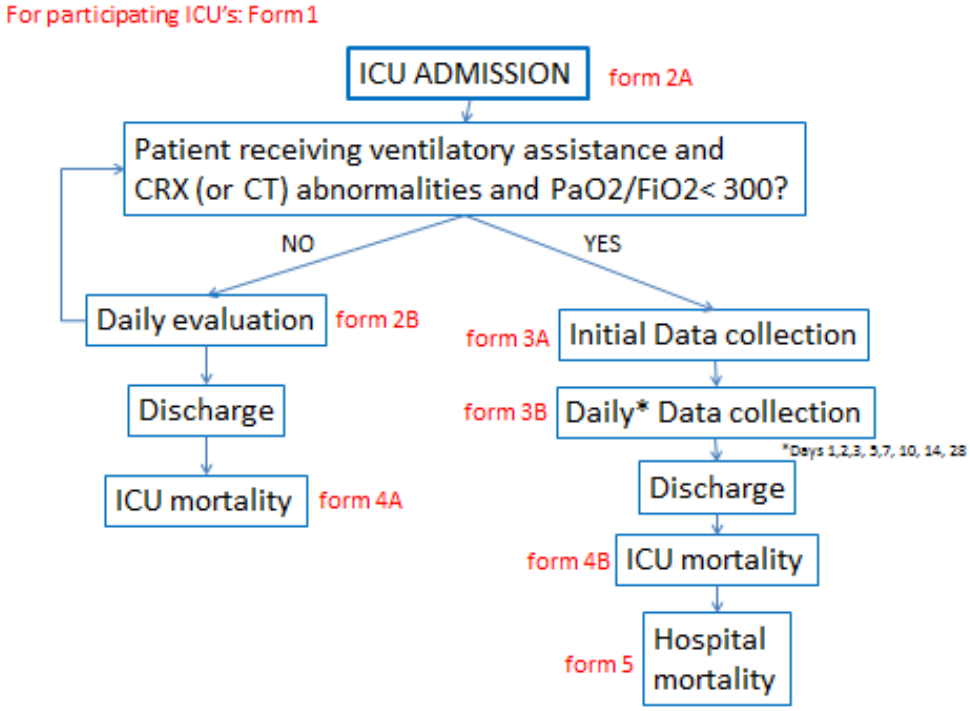
Large observational study to UNderstand the Global impact of Severe Acute respiratory FailurE – ['LUNG-SAFE' study]

APPENDIX: DATA COLLECTION FORMS

PATIENT FLOW CHART



General study flow chart

FORM 1: STUDY ICU ORGANIZATIONAL DATA[1]

INSTITUTION: _____

Mailing Address: _____

Phone_____ Fax _____

Contact person #1: _____ Email:_____

Contact person #2: _____ Email:_____

Medical Director:_____ Specialist Intensivist: ☐YES ☐ NO

Type of hospital: ☐ University/Academic ☐ Non-University

Number of beds in the hospital: _____

Number of beds in use in the ICU at commencement of study: _____

Total number of admissions to the ICU in last calendar year: _____

Total number of ICU beds in the hospital: _____

Was this ICU involved in research activities (other than surveys) in the last 5 years? ☐ YES ☐ NO

Average number of Health Professionals **present** in the ICU[2]:

	Daytime	Night time
Staff Physician		
Resident		
Fellows		
Nurses		
Occupational Therapists		
Physiotherapists		
Pharmacists		
Respiratory Therapists (if applicable)		

[1] This form will be completed once by each participating ICU. The site data collector will complete this as part of the agreement to participate, once they have satisfactorily completed the online training program we have out in place.

[2] This number may be less than 1.0, particularly for allied health professionals such as physiotherapists. If so, please estimate amount of time as a proportion of a full working day spent by these personnel in the ICU.

Patient Initials: _____ **Study ID: _____** **Date of Data collection:_____**

FORM 2A: INITIAL EVALUATION AT ICU ADMISSION[3]

Date of ICU Admission: _ _ / _ _ / 201_ _ _ : _ _ (24 h clock)

Patient ID Number:_____

Age:_ _ yrs[4] **Gender** □ Male □ Female

Type of Admission (check all that Apply): □ Medical □ Surgical: □ Elective □ Emergency □ Trauma

Does this patient have Severe Hypoxaemic Respiratory Failure?

A. Is this patient receiving:

a. Invasive mechanical Ventilation with PEEP ≥5 cmH_2O	□ YES	□ NO
b. Non-invasive Ventilation with EPAP ≥5cmH_2O	□ YES	□ NO
c. CPAP ≥5 cmH_2O	□ YES	□ NO

NOTE: If 'YES' to 'A', then data collector automatically directed proceed 'B'.

B. Severity of Hypoxemia:

a. Arterial PO_2 _____ OR Arterial O_2 Saturation _____

b. Inspired Oxygen Fraction _____

C. Chest X-Ray ot CT scan findings:

a. Not done
b. Normal Lung fields
c. Abnormal lung fields

NOTE: If patient is receiving invasive or non-invasive ventilation or CPAP and PaO_2/FiO_2 ratio < 300 mmHg and CRX or CT scan shows abnormal lung fields, then data collector is automatically directed to complete <u>Form #3</u>

If criteria not fulfilled, data collector automatically directed to proceed to Form #2B re-evaluate the patient daily [Days 1, 2, 3, 5, 7,14 and 28] at 10 AM.

[3] Assessment performed at 10 am on day of ICU admission

[4] If age <16, data collector will be informed by program that patient not eligible for recruitment..

Patient Initials: _____ **Study ID: _____** **Date of Data collection:_____**

FORM 2B: DAILY RE-EVALUATION[5]

1. Has patient been discharged from ICU? □ YES □ NO

2. Has patient died in ICU? □ YES □ NO

NOTE: If 'YES' to Q1 or Q2 then data collector automatically directed to complete Form #4A

3. Does this patient have Severe Hypoxaemic Respiratory Failure?

A. Is this patient receiving:

a. Invasive mechanical Ventilation with PEEP ≥5 cmH_2O	□ YES	□ NO
b. Non-invasive Ventilation with EPAP ≥5cmH_2O	□ YES	□ NO
c. CPAP ≥5 cmH_2O	□ YES	□ NO

NOTE: If 'YES' to QA, then data collector automatically directed proceed QB.

B. Severity of Hypoxemia:

a. Arterial PO_2 _____ OR Arterial O_2 Saturation _____

b. Inspired Oxygen Fraction _____

C. Chest X-Ray or CT scan findings:

a. Not done
b. Normal Lung fields
c. Abnormal lung fields

NOTE: If patient is receiving invasive or non-invasive ventilation or CPAP and PaO_2/FiO_2 ratio < 300 mmHg and CRX or CT scan shows abnormal lung fields, then data collector is automatically directed to complete Form #3

If not redirected to complete Form #3, data collector requested to continue daily [Days 1, 2, 3, 5, 7,14 and 28] re-evaluations until ICU discharge/death at which time they will be prompted to complete Form #4.

[5] It is important that ALL PATIENTS who are in the ICU at 10AM each day are assessed, independently of their status. No other data are required for patients who are not receiving assisted ventilation.

Patient Initials: _____ **Study ID: _____** **Date of Data collection:_____**

FORM 3A: PATIENT DATA COLLECTION FORM – Study Day 1 [6]

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
□ OR/Recovery □ Study Hospital (Ward) □ Study Hospital (Other ICU)
□ Other, please specify _____

If patient transferred from another hospital

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 □ Active Neoplasm □ Hematologic neoplasm
□ Diabetes Mellitus □ Heart failure: NYHA classes III-IV
□ Chronic Renal Failure □ Immunosuppression[7] □ Chronic liver failure (Child-Pugh Class C)

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		

[6] Assessment completed once at time that patient fulfills criteria for hypoxaemic respiratory failure

[7] Includes drugs such as cyclosporine, azathioprine, rituximab or cancer chemotherapy, steroids (except for adrenal insufficiency replacement)

Date of the insult: _ _ / _ _ / _ _ _ _ OR Not Known ☐

Can hypoxemia be entirely explained by cardiac failure?
☐ Yes ☐ No

If NO risk factor is present, which method was used to rule out the cardiac origin of the disease (check all that apply):

	Echocardiography
	Pulmonary artery catheter
	Transpulmonary thermodilution (e.g., PiCCO)
	Other (specify):

Does the patient have ARDS?
☐ Yes ☐ No

Patient Initials: _____ **Study ID: _____** **Date of Data collection:_____**

FORM 3B: DAILY PATIENT DATA COLLECTION FORM[8]

1. Has patient been discharged from ICU or died? □ YES □ NO

NOTE: If 'YES' to Q1 then data collector automatically directed to complete Form #4B

IF ANSWER 'NO; to Q1, then directed to continue to complete Form 3B

Arterial Blood Gas *(± 2 hours from time of recorded Vent settings)***:**

pH: __ . __ __ PaO_2: __ __ __ mmHg/KPa **$PaCO_2$: __ __ __** mmHg/KPa **FiO_2: __ . __ __**

If no Arterial Blood Gas Analysis: SaO2: __ __ __ % **FiO2: __ . __ __**

Bilateral opacities on the Chest X-Ray or on the CT scan:
☐ YES ☐ NO ☐ No CXR today

Number of quadrants involved on Chest X-Ray:
Score ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ No CXR today

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

SOFA Score	Day 1	NOT AVAILABLE
Arterial PO_2 (mmHg/KPa)		□
Inspired Oxygen Fraction (FiO_2)		□
Arterial oxygen saturation (SpO_2)		□
Glasgow Coma Scale (3-15)		□
Mean Arterial Pressure (mmHg)		□
Dopamine infusion (μg/min)		□
Dobutamine infusion (μg/min)		□
Noradrenaline infusion (μg/min)		□
Adrenaline infusion (μg/min)		□
Platelet Count($\times 10^3/mm^3$)		□
Total Bilirubin (mg/dL)		□
OR Total Bilirubin (μmol/L)		□
Creatinine (mg/dL)		□
OR Creatinine (μmol/L)		□
OR Urine Output (mL/day)		□

[8] Data is collected at at 10am on Days 1,2,3,5,7 inclusive, Day 10, 14 and weekly thereafter until ICU discharge/death. Form should be completed on day of ICU discharge/death.

Mechanical Ventilation (record settings at 10am):

☐ Invasive ☐ Non-invasive ☐ CPAP ☐ Only O_2 ☐ None

Please record appropriate ventilator settings as close to 10 AM (± 1 hour) as possible

Variable	Volume A/C	PC/BIPAP/APRV	SIMV	PRVG	PSV	NAVA	HFO	CPAP	T-Tube
RR (set) (if HFO, enter hertz)	__	__	__	__			__ Hz		
RR (Total)	__	__	__	__	__			__	__
PEEP (cmH_20) (EPAP if NIV, P_{low} for APRV)	__	__	__	__	__			__	
FiO_2 %	___%	___%	___%	___%	___%		___%	___%	___%
Tidal Volume*** (cc) (T-low for APRV; delta P for HFO	___ml	___ml	___ml	___ml	___ml		__		
Plateau Pressure (cmH_20) (T-high for APRV)	__	__	__	__					
Peak Inspiratory Pressure (PIP) (cmH_20) (P_{high} for APRV)	__	__	__	__					
Mean Airway Pressure (MAP) (cmH_20)	__	__	__		__		__	__	__
Is the patient triggering the Ventilator	__	__	__						

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

☐	Prone positioning	☐	Inhaled vasodilators (e.g., nitric oxide, epoprostenol)
☐	Recruitment maneuvers	☐	Extracorporeal CO_2 removal ($ECCO_2R$)
☐	Extracorporeal membrane oxygenation (If yes: V-V or A-V or V-A)	☐	CT scan
☐	High dose corticosteroids	☐	Alveolar surfactant
☐	Almitrine besylate	☐	Renal Replacement Therapy
☐	Continuous Sedation	☐	Continuous Neuromuscular Blocking Agents
☐	Oesophageal pressure monitoring	☐	Pulmonary Artery Catheter (If yes: mean pulmonary arterial pressure:_____)
☐	Lung Ultrasound	☐	Tracheostomy

FORM 4A: OUTCOMES – ICU DISCHARGE/DEATH[9]

ICU Outcome
□ Alive □ Dead

Date of ICU discharge/Death: _ _ / _ _ / _ _ _ _

[9] This data is collected on <u>all</u> patients enrolled in Study

Patient Initials: _____ **Study ID: _____** **Date of Data collection:_____**

FORM 4B: OUTCOMES – ICU DISCHARGE/DEATH[10]

ICU Outcome
□ Alive □ Dead

Date of ICU discharge/Death: _ _ / _ _ / _ _ _ _

Discharged to:
□ Other ICU □ Hospital Ward □ Intermediate Care Unit □ Hospital Discharge (go to Form 5)

Did the patient develop additional risk factors for ARDS (except those in form 3A)?
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):		

Could patient hypoxemia be entirely explained by cardiac failure?
☐ Yes ☐ No

Which method was used to rule out the cardiac origin of the disease (check all that apply):

	Echocardiography
	Pulmonary artery catheter
	Transpulmonary thermodilution (e.g., PiCCO)
	Other (specify):

Did the patient have ARDS at any stage of their ICU stay?
☐ Yes ☐ No

Respiratory status at ICU Discharge (Check all that apply):
□ Tracheostomy □ Non-invasive ventilation □ CPAP □ Oxygen therapy
Date of liberation from MV: _ _ / _ _ / _ _ _ _

Was a lung biopsy performed ? □ Yes □ No
If yes, day lung biopsy performed*: _ _ / _ _ / _ _ _ _
If yes, provide histopathological pattern:

[10] This data is collected on patients fulfilling criteria for severe hypoxemic respiratory failure

□ Diffuse alveolar damage
□ Diffuse alveolar hemorrhage
□ Eosinophilic infiltration
□ Bronchiolitis obliterans organizing pneumonia
□ Lung fibrosis
□ Other Specify: _

If patient did not survive:
What was the most important factor leading to ICU Death (Tick 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/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 a autopsy (i.e. post mortem) examination
□ Yes □ No

If an Autopsy was performed, what did lung histology demonstrate [Tick all that apply]
□ Pneumonia
□ Diffuse Alveolar Damage
□ Pulmonary Oedema
□ Atelectasis
□ No lung pathology
□ Other (Specify) _____

Patient Initials: _____ **Study ID: _____** **Date of Data collection:_____**

FORM 4C: ADDITIONAL DISCHARGE FORM FOR PATIENT WITHOUT RISK FACTORS 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: _ _ _ _

Was the patient taking pneumotoxic medications* before the development of ARDS? ☐ Yes ☐ No

If yes, provide name of the drugs (check all that apply)

☐ Amiodarone

☐ Methotrexate

☐ Hydrochlorothiazide

☐ Tyrosine kinase inhibitors

☐ Chemotherapy agents: _ _ _ _ _ _ _ _

☐ Other: _ _ _ _ _ _ _ _ _

* see www.pneumotox.com for more information

Was a final etiology for ARDS obtained? ☐ Yes ☐ No

If yes, specify: _

Was a chest CT-scan performed? ☐ Yes ☐ No

If yes, day chest CT-scan performed: _ _ / _ _ / _ _ _ _

If yes, provide CT-scan patterns present (check all that apply):

☐ *Honeycombing*

☐ *Ground class attenuation*

☐ *Traction bronchiectasis*

☐ *Interlobular septal thickening*

☐ *Air space consolidation including atelectasis*

☐ *Other* Specify: _

*if several CT were performed: results of the nearest from the ARDS diagnosis

Patient Initials: _____ **Study ID: _____** **Date of Data collection:_____**

FORM 5: OUTCOMES – HOSPITAL OUTCOME[11]

Hospital (or 90 day) Outcome (whichever event occurs first)
□ Alive □ Dead
Date of hospital discharge: _ _ / _ _ / _ _ _ _

[11] This data only collected on patients that fulfilled fulfilling criteria for severe hypoxemic respiratory failure