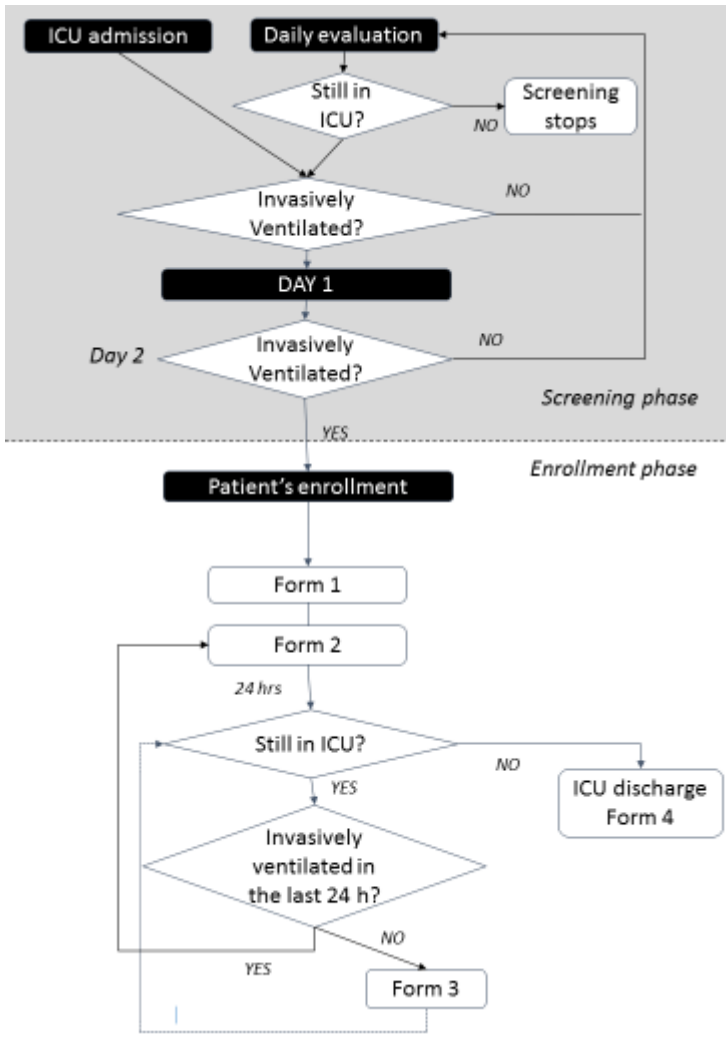


WEAN SAFE



Data Collection Forms



Study ID: _____

Date of Data collection: _____

FORM 0: - ORGANIZATIONAL DATA OF THE PARTICIPATING ICU
TO BE FILLED ONLY ONCE FOR THE STUDY

0.1 Name of the INSTITUTION: _____

0.2 Mailing Address: _____

0.3 Phone _____

0.4 Contact person #1: _____

0.5 Email: _____

0.6 Contact person #2: _____

0.7 Email: _____

0.8 ICU Medical Director: _____

0.9 Open ICU Closed ICU [ONE SELECTION ONLY]

0.10 Type of hospital: University/Academic Non-University [ONE SELECTION ONLY]

Type of ICU (check all that apply):

0.11 Medical

0.12 Respiratory ICU

0.13 Surgical

0.14 Cardiothoracic

0.15 Neurosurgical

0.16 Other specialty

0.17 Total number of beds in the hospital: _____

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

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

0.20 Total number of ICU beds in the hospital (including all ICUs, also not involved in this study, excluding intermediate care): _____

0.21 Was this ICU involved in research activities (other than surveys) in the last 5 years?
 YES NO [ONE SELECTION ONLY]

0.22 Is there a step-down/intermediate care unit in your hospital?
 YES NO [ONE SELECTION ONLY]

0.23 Does this hospital have a dedicated weaning facility within the hospital?
 YES NO [ONE SELECTION ONLY]

Average number of Health Professionals **present** in the ICU¹:

	Daytime	Night time
Staff Physicians		
Doctors in training/Non-staff		
Nurses/Nurse practitioners		
Physician assistants		
Occupational Therapists		
Physiotherapists		
Pharmacists		
Respiratory Therapists		

Which UNITS are used for the following:

0.40 **Noradrenaline/norepinephrine:** mcg/min mcg/kg/min mg/hour [ONE SELECTION ONLY]

0.41 **Adrenaline/epinephrine:** mcg/min mcg/kg/min mg/hour [ONE SELECTION ONLY]

0.42 **Dopamine:** mcg/min mcg/kg/min mg/hour [ONE SELECTION ONLY]

0.43 **Dobutamine:** mcg/min mcg/kg/min mg/hour [ONE SELECTION ONLY]

0.44 **Blood gases?** mmHg kPa [ONE SELECTION ONLY]

0.45 **Platelets:** 10³/mm³ 10⁹/L [ONE SELECTION ONLY]

0.46 **Hemoglobin:** g/100 ml g/L mmol/L [ONE SELECTION ONLY]

0.47 Height: inch cm [ONE SELECTION ONLY]

0.48 Weight: lbs kg [ONE SELECTION ONLY]

0.49 Do you use written/electronic sedation protocols? YES NO [ONE SELECTION ONLY]

0.50 Do you use a sedation scale? YES NO [ONE SELECTION ONLY]

0.51 (IF YES: SAS RASS Ramsay Other _____)

0.52 Does your ICU have weaning protocols for patients ventilated > 24 hours? YES NO [ONE SELECTION ONLY]

0.53 If yes: Physician driven Nurses driven RT driven [ONE SELECTION ONLY]

0.54 Please upload your protocol.

0.55 Do you use automated weaning system?

YES NO [ONE SELECTION ONLY]

0.56 If yes, please indicate which one: _____

¹ 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.

Study ID: _____

Date of Data collection: _____

DAILY SCREENING FORM

Patient's initials: _____

Gender: M F

Year of Birth: _____

First day of ventilation in the present ICU __ [FIRST DAY OF VENTILATION] _____

Are there any exclusion Criteria present? Yes No

Date	Is this patient in ICU today?	Is this patient receiving Invasive Mechanical Ventilation today
[FIRST DAY OF VENTILATION] +1	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
[FIRST DAY OF VENTILATION] +2	Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/> If Yes PATIENT ENROLLED!

ICU Outcome (non-enrolled Patients)

Alive at ICU Discharge: Yes No

FORM 1: - TO BE COMPLETED FOR ALL INVASIVELY VENTILATED PATIENTS ON STUDY DAY 1

Sub Form "GENERAL"

1.1 Date of enrollment (between 7AM and 10AM on study day 1): __/__/__ [FILLED AUTOMATICALLY FROM THE FORM BEFORE]

1.2 Date and hour of commencement of IMV: __/__/__(DD/MM/Year)

1.3 at _____(24 hour clock)

1.4 Date of ICU admission in the current episode: __/__/201__ (DD/MM/Year)

1.5 Gender: M F [ONE SELECTION ONLY]

1.6 Age: _____

What was the **main category** of ICU admission? (SELECT ONLY ONE OPTION)

1.7 Medical

1.8 Scheduled Surgery

1.9 Emergency surgery (excluding Trauma)

1.10 Trauma [with or without surgery]

1.11 Monitoring (e.g. in situ thrombolysis, desensitization), or post non-surgical procedure (including PCI, bronchoscopy)

Hospital Admission

1.12 Date of presentation in current Hospital: __/__/201__ (DD/MM/Year)

1.13 Height (first documented at ICU admission): _____

1.14 Weight (first documented at ICU admission): _____

1.15 Residence Status prior to hospital admission [ONE SELECTION ONLY]

Home

Other healthcare facility

Nursing home

Unknown

Homeless

1.16 **Admission Source:** [ONE SELECTION ONLY]

Other ICU

Ward

ER

OR/Recovery

Other, please specify

1.17 Was the patient previously intubated for greater than 24 hours during this hospital admission prior to enrollment?

YES

NO

[ONE SELECTION ONLY]

1.18 Was the patient previously enrolled in this study? YES NO

[ONE SELECTION ONLY]

1.19 (If yes, indicate the patient's **previous study number** _____)

Co-morbidities present before ICU admission (check all that apply):

1.20 COPD (If known, GOLD: I II III IV)

1.21 Interstitial Lung Disease

1.22 Other chronic lung disease

- 1.23 Asthma requiring home inhaled or oral medications
 Hematologic neoplasm 1.26 Bone marrow transplant
 oral hypoglycaemic therapy therapy
- 1.24 Active solid organ Neoplasm² 1.25
 1.27 Diabetes Mellitus requiring insulin or
- 1.28 Heart failure: NYHA classes III-IV 1.29 Chronic Renal Failure (if selected: 1.29a Requiring dialysis)
 1.30 Immunosuppression³
- 1.31 Chronic liver failure (1.32 Child-Pugh Class C) 1.33 Congenital/Acquired Myopathies/Neuropathies
 1.34 alcohol abuse 1.35 active smoker 1.36 pulmonary hypertension 1.37 kyphoscoliosis
 with respiratory dysfunction

1.38 **Pregnancy** [ONE SELECTION ONLY] Yes No Unknown

1.39 **Known or suspected diagnosis of dementia?** [ONE SELECTION ONLY]

None Mild Moderate/severe

1.40 **Clinical Frailty Scale Score (in the 2 months prior to first ICU admission)** [ONE SELECTION ONLY]

1. Very fit — robust, active, energetic, well motivated and fit; exercise regularly; most fit group for their age
2. Well — without active disease, but less fit than people in category 1
3. Managing Well, with treated comorbid disease — disease symptoms are well controlled
4. Apparently Vulnerable —not frankly dependent, patients “slowed up” or have disease symptoms
5. Mildly Frail — with limited dependence on others for instrumental activities of daily living
6. Moderately Frail — help is needed with all outside activities and with keeping house, i.e. in both instrumental and non-instrumental activities of daily living
7. Severely frail — completely dependent on others for personal care, from whatever cause (physical or cognitive).
8. Very Severely Frail – Completely dependent, approaching the end of life. Terminally Ill – life expectancy < 6 months, whether or not evidently frail.

What is/are the cause(s) of the patient’s ICU admission (check all that apply)?

- 1.41 Hypercapnic Respiratory Failure
 1.42 Hypoxaemic Respiratory Failure
 1.43 Sepsis/septic shock
 1.44 Cardiogenic pulmonary edema
 1.45 Cardiac arrest
 1.46 Emergency surgery
 1.47 Elective surgery (1.48 CARDIAC 1.49 ABDOMINAL 1.50 THORACIC
 1.51 NEUROSURGICAL 1.52 Other _____)
 1.53 Shock (other than septic)
 1.54 Trauma
 1.55 Neurologic impairment
 1.56 Drug overdose
 1.57 Airway protection
 1.58 Other (_____))
 1.59 Metabolic/electrolyte

² Excluding non-melanoma skin cancer

³ Includes drugs such as cyclosporine, azathioprine, rituximab or cancer chemotherapy, steroids (except for adrenal insufficiency replacement)

Study ID: _____

Date of Data collection: _____

FORM 2: - DAILY DATA COLLECTION FORM

THIS FORM HAS TO BE FILLED EVERY DAY, REPORTING DATA COLLECTED BETWEEN 7-10 am

2.1a Was this patient in the ICU in the last 24 hours? YES NO (Go to form 4) [ONE SELECTION ONLY]

2.1b Was Patient invasively ventilated in the last 24 hours? YES NO (Go to form 3) [ONE SELECTION ONLY]

2.2 Patient's interface: ETT Tracheostomy Not invasively ventilated anymore [ONE SELECTION ONLY]

2.3 Sedation level (before sedation interruption): [ONE SELECTION ONLY]

_____ RASS SASS RAMSAY Not measured

2.4 Was there a sedation interruption in the last 24 hours: [ONE SELECTION ONLY]

Yes No

What is the current (at the time of evaluation) level of ventilator assistance received (if on separation attempt, please give prior level of assistance)?

Full support: Volume A/C PC/BIPAP/APRV SIMV PRVG

Partial support: PSV NAVA

Minimal support: CPAP T-Tube Other (specify)

Please record ventilator settings:

2.14 Peak _____ 2.15 Plateau (if different) _____
2.16 RR (set) _____ 2.17 RR (total) _____ 2.18 PEEP (cmH2O) _____
2.21 FiO2 _____ 2.22 Actual Tidal volume _____ 2.23 p0.1 _____ (if measured)

Arterial Blood Gas (as close as possible to above vent settings, if measured):

2.24 pH: __ . __ __ 2.25 PaO₂: __ __ __
2.26 PaCO₂: __ __ __ 2.27 Lactate __ . __ __

2.28 If no Arterial Blood Gas Analysis: Pulse Oximeter SpO₂: __ __ __ %

2.29 **What is the lowest level of assistance received in the last 24 hours? IF DIFFERENT FROM ABOVE**
[ONE SELECTION ONLY]

Assistance level not different from above

Full support: Volume A/C PC/BIPAP/APRV SIMV PRVG

Partial support: PSV NAVA

Minimal support: CPAP T-Tube Other (specify)

Extubation: Accidental Extubation Planned Extubation

2.30 Peak _____ 2.31 Plateau (if different) _____ [if cmv]

2.31 Pressure support level _____ [if PSV]

2.32 RR (set) _____ 2.33 RR (total) _____ 2.34 PEEP (cmH2O) _____

2.35 FiO₂ _____ 2.36 Actual Tidal volume _____ 2.37 p0.1 _____ (if measured)

2.38 How long was this level maintained for? _____ hours Start time _____

2.39 What was the reason for termination of lower level of support?

- Pre-planned termination Patient deterioration Other (Specify)_____

Arterial Blood Gas (if measured during reduced support):

2.40 pH: __ . __ __ 2.41 PaO₂: __ __ __
2.42 PaCO₂: __ __ __ 2.43 Lactate __ . __ __

2.44 If no Arterial Blood Gas Analysis: Pulse Oximeter SpO₂: __ __ __ %

2.45 Was this a spontaneous breathing trial (SBT), to predict success in separating the patient from the ventilator?

- YES NO [ONE SELECTION ONLY]

SOFA Score (every third day from day 1, 4, etc.)**Values****NOT AVAILABLE**

(Please give worst value in the last 24 hours)

Glasgow Coma Scale (3-15)

2.46 motor

2.47 eye

2.48 verbal

1

2.49 Platelet Count(UNITS)

2.50 Total Bilirubin (if measured)

2.51 Creatinine (if measured)

2.52 OR Urine Output (mL/day)

2.53 Mean Arterial Pressure (mmHg)

2.54 Dopamine infusion

2.55 Dobutamine infusion

2.56 Noradrenaline infusion

2.57 Adrenaline infusion

2.58 Others vasopressors? (Yes/No) or dosage?

2.59 PDE inhibitors (Yes/No) or dosage?

In the last 24 hours, did the patient receive any of the following drugs:

2.60 Sedatives[ONE SELECTION ONLY]:

Continuous Intermittent None

2.61 Opioids[ONE SELECTION ONLY]:

Continuous Intermittent None

2.62 NM blockers[ONE SELECTION ONLY]:

Continuous Intermittent None

2.63 Steroids[ONE SELECTION ONLY]:

High dose Low dose None

2.64 Diuretics[ONE SELECTION ONLY]:

High dose Low dose None 2.65 Renal replacement therapy [ONE SELECTION ONLY] YES NO2.66 Is the patient receiving ECMO/ECCO2R YES NO Blood flow_____ l/min

PART B: - TO BE FILLED FOR PATIENTS WITH PEEP < 10 cm H2O, and FiO2 < 50%, if they are not receiving neuromuscular blockers or high doses of vasopressors (> 0.2 mcg/kg/min of noradrenaline or equivalent)

What are the reasons for not separating the patient from the ventilator according to the attending physician (check all that apply)?

- 2.67 Unresolved surgical condition
- 2.68 Unresolved respiratory failure
- 2.69 Upper airway protection
- 2.70 Decreased level of consciousness
- 2.71 Agitation/ delirium
- 2.72 Cardiac failure / Fluid Overload
- 2.73 Hemodynamic instability
- 2.74 Muscle weakness
- 2.75 Planned intervention requiring airway protection
- 2.76 Failed spontaneous breathing trial
- 2.77 Recent [< 24 hours] re-intubation
- 2.78 Excessive secretion
- 2.79 Weak cough

2.80 **Maximum Inspiratory Pressure (if measured in the last 24 hours)** _____ cmH2O

2.81 **Is this patient considered in weaning phase according to the attending physician?**

Yes No Uncertain Unknown [ONE SELECTION ONLY]

2.82 **Amount of secretions:** none/mild moderate abundant [ONE SELECTION ONLY]

2.83 **Cough strength:** weak intermediate normal/strong
 NOT RECORDED [ONE SELECTION ONLY]

2.84 **Was the patient out of the bed last 24 hours?** Yes No [ONE SELECTION ONLY]

2.85 **Did the patient do mobility exercise last 24 hours?**

Yes, active Yes, passive No [ONE SELECTION ONLY]

2.86 Current heart rate _____

2.87 Current systolic blood pressure _____

2.88 Current diastolic blood pressure _____

2.89 Fluid balance in last 24 hours _____

Study ID: _____

Date of Data collection: _____

FORM 3: - DAILY DATA COLLECTION FORM FOR PATIENTS NOT CONNECTED TO THE VENTILATOR IN THE LAST 24 HOURS

IN THE LAST 24 HOURS DID THE PATIENT RECEIVE ANY OF THE FOLLOWING? (Check all that apply)

- 3.1 Face mask/Nasal cannula low flow oxygen (<15)
- 3.2 NIV/CPAP **via** Helmet **interface**
- 3.3 NIV/CPAP **via** Face/Nose Mask **interface**
- 3.4 High Flow nasal cannula
- 3.5 None of the above

IF YES, WHAT WAS THE REASON? (Check all that apply)

- 3.6 Hypoxia
- 3.7 Hypercapnia
- 3.8 Respiratory distress
- 3.9 Prophylaxis
- 3.10 Restoration of home **ventilatory support** (including Sleep Apnea Syndrome)

Study ID: _____

Date of Data collection: _____

FORM 4: - OUTCOMES – ICU DISCHARGE/DEATH

ICU Outcome

4.1 Alive Dead [ONE SELECTION ONLY]

4.2 Date of ICU discharge/Death: __/__/____ (DD/MM/Year)

For pts discharged alive

4.3 Discharged to: [ONE SELECTION ONLY]

This Hospital: Other ICU Intermediate Care Unit Weaning unit Hospital Ward

Other Hospital: ICU Intermediate Care Unit Weaning unit Hospital Ward

Other Location: Home Rehabilitation facility Other (Specify) _____

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

4.4 Intubated 4.5 Tracheostomy 4.6 Non-invasive ventilation

4.7 Oxygen therapy 4.8 No oxygen therapy

4.9 Level of physical Dependence (at discharge) [ONE SELECTION ONLY]

Independent Partially Dependent Completely Dependent

Changes in Goals of Care

4.10 Was there a pre-existing order limiting life-sustaining measures prior to ICU admission?
(E.g. no CPR/withhold/withdraw)

4.11 Was there a decision to limit a life sustaining measure at any time during the ICU stay?
 Yes No Not legally available [ONE SELECTION ONLY]

If answer to 4.11= "yes"

What was the life sustaining measure limited? [CHECK ALL THAT APPLY]

4.12 No CPR

4.13 No re-intubation

4.14 No re-admission to ICU

4.15 ICU trial

4.16 Full comfort care [i.e. no organ support]

4.17 Extubation with full comfort and/or palliative care.

4.18 Did a difficulty in weaning influence the decision to limit life-sustaining measures? [ONE SELECTION ONLY]

No

Yes – Sole/major reason

Yes – One of a number of reasons

4.19 Date of decision for 'No CPR' measures in event of cardiac arrest: __/__/____

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

Co-Enrollment in another Study

4.21 Was this patient co-enrolled in another study Yes No [ONE SELECTION ONLY]

4.22 If patient was co-enrolled, was there a protocol for weaning from mechanical ventilation
 Yes No [ONE SELECTION ONLY]

If ICU outcome= "alive"

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

4.23 Alive Dead

[ONE SELECTION ONLY]

4.24 Date of hospital discharge: __/__/_____