# SAnDMAN

**S**edation, **A**nalgesia a**n**d **D**elirium **MAN**agement: an international audit of adult medical, surgical, trauma, and neuro-intensive care patients

# Manual of Operations

SAnDMAN Investigators and Contact Information

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## ABBREVIATIONS

| | | | |
|---|---|---|---|
| ARDS | Acute Respiratory Distress Syndrome | l/min | Liters per minute |
| BiPAP | Bi-level Positive Airway Pressure | kg | kilogram |
| BIS | Bispectral Index | MAAS | Motor Activity Assessment Scale |
| BPS | Behavioural Pain Scale | MAP | Mean Arterial Pressure |
| CAM-ICU | Confusion Assessment Method - ICU | MDAS | Memorial Delirium Assessment Scale |
| CPAP | Continuous Positive Airway Pressure | mg | milligram |
| CPAx | Chelsea critical care physical assessment tool | mmHg | millimetre of mercury |
| CPOT | Clinical Pain Observation Tool | MMSE | Mini Mental State Examination |
| COVID-19 | Corona Virus Disease 2019 | MV | Mechanical Ventilation |
| DD/MM/YYYY | Date/Month/Year | NA | Not available |
| DMSS | Delirium Motor Subtype Scale | NEECHAM | NEElon and CHAMpagne Confusion Scale |
| DSM-V | Diagnostic and Statistical Manual of Mental Disorders, 5$^{th}$ Edition | NIRS | Near-infrared spectroscopy |
| EEG | Electroencephalography | NRS | Numeric Rating Scale |
| ECMO | Extracorporeal Membrane Oxygenation | NSAIDs | Non-steroidal anti-inflammatory drugs |
| eCRF | Electronic Case Report Form | NuDeSC | Nurses' Delirium Screening Checklist |
| e.g | Exempli gratia (for example) | NVPS | Non-Verbal Pain Scale |
| etc | Et cetera (and other similar things) | $PaO_2$ | Partial Pressure of Oxygen |
| $FiO_2$ | Fraction of Inspired Oxygen | PFIT | Physical Function ICU Test |
| FSS-ICU | Functional Status Score for the Intensive Care Unit | PO | Per Os (per mouth) |
| GCS | Glasgow Coma Score | PRN | "Pro Re Nata" (As needed or as the situation arises) |
| HDU | High Dependency Unit | Q | Question |
| HFO | High frequency oscillation (or jet ventilation) | RASS | Richmond Agitation and Sedation Scale |
| hh:mm | Hours:minutes | SARS-CoV2 | Severe Acute Respiratory Syndrome-related Coronavirus 2 |
| ICD-10 | International Classification of Diseases, 10th Revision | SAS | Riker Sedation-Agitation Scale |
| ICDSC | Intensive Care Delirium Screening Checklist | SBT | Spontaneous Breathing Trial |
| ICP | Intracranial Pressure | SC | Subcutaneous |
| ICU | Intensive care unit | SIMV | Synchronized Intermittent Mandatory Ventilation |
| ID | Identification/identity | $SO_2$ | Oxygen saturation |
| i.e | Id est (in other words) | SOFA | Sequential organ failure assessment |
| IM | Intramuscular | SOMS | Surgical ICU Optimal Mobilisation Score |
| IMV | Invasive mechanical ventilation | T | Transdermal |
| IV | Intravenous | TOF | Train of four |
| IV-B | Intravenous bolus | VAS | Visual Analogue Scale |
| IV-C | Intravenous continuous infusion | VDS | Verbal Descriptor Scale |

**CENTER AND PATIENT NUMBER**

Site number: Each ICU will be assigned a unique site ID number (001, 002, 003, etc). If there is more than one ICU in your hospital, each ICU will be assigned a unique Site number.

If you are an investigator in several ICUs, your user account will be linked to various ICUs, you will have to select the appropriate site when enrolling a patient and completing ICU site demographics. The site will either appear with the name provided by you when registering (MICU, General ICU, etc) or a number.

Patient number: Each patient at a site will be assigned a sequential number, from 01 to 20 (e.g., 01, 02, 03, etc.)

The ID number for each patient will be a unique 5-digit number. E.g., the ID number for sequential patients enrolled at center 001 would be 001-01, 001-02, 001-03, etc.

**INCLUSION CRITERIA**

Include the following patients:

- All adults (≥18 years)
- Admitted to a participating ICU
- Invasively mechanically ventilated for ≥12 hours
- Medical, surgical, cardiac, obstetric, neurological/neurosurgical patients, trauma, and burns,

**EXCLUSION CRITERIA**

There are no exclusion criteria

**ALL DATES** should be entered as day/month/year (DD/MMM/YYYY) e.g. 01/JAN/2019

**DURATION of PATIENT ENROLLMENT**

Data will be collected for a 7-day period (labelled study days 1-7) selected by the site investigator. We will include the last 20 consecutive patients per centre who are admitted to ICU and mechanically ventilated in the 3 months before the study start date. For these patients, data collection will start on the day of initiation of mechanical ventilation.

The specific period of data collection (i.e., the particular month) will be selected by the site investigator.

Patients who are admitted on weekends may have their data collected on the next weekday.

ICU data will be collected until one of the following endpoints:

1. Liberation from mechanical ventilation for 24 hours or more; or
2. ICU discharge if they are transferred out of the ICU mechanically ventilated; or
3. Death in ICU; or
4. A maximum of 7 days following the start of invasive mechanical ventilation.

For ICU survivors, please enter the dates of ICU discharge, and hospital disposition (discharge or death).

## FORM 1: SITE DEMOGRAPHICS

This form should be completed **once** for each ICU participating in SAnDMAN. If 2 or more ICUs in one hospital are participating, please complete one FORM 1 for each ICU.

### A. ICU DEMOGRAPHIC DATA

1. Enter the name of your hospital.
2. Enter the name of the city where your hospital is located.
3. Enter the name of the country where your hospital is located.
4. Select the one most appropriate description of your hospital.
   - If your hospital is associated with a medical university/school to some degree, select '*University affiliated hospital*'.
   - If your hospital is in a community or district setting and provides continuing medical education to its medical residents and trainees, select '*Community/District hospital - Teaching'*.
   - If your hospital does not provide continuing medical education to its medical residents and trainees, select '*Community/district hospital - Non-teaching'*.
   - If your hospital's description is not listed as an option provided, select '*Other'.*
5. Select the one most appropriate range that includes the total number of beds your hospital provides.
6. Select the one most PREDOMINENT type of patient population for whom you provide care in your ICU.
   - If your ICU provides care for more than one type of patient, select '*Mixed ICU*'.
   - If the population for whom your ICU provides care is not listed as an option, select '*Other'*.
7. Select the one most appropriate model of care of your ICU.
   - If your ICU's model of care is not listed as an option, select '*Other'*.
8. Select the one most appropriate range that for the number of beds in the ICU that is participating in SAnDMAN.
9. Select the one most appropriate range that reflects the number of ventilators available for invasive mechanical ventilation in your ICU.
10. Select the one most appropriate range that represents the number of annual admissions to your ICU.

## B. ICU STAFFING INFORMATION

1. Select the one most appropriate nurse to patient ratio (on average) for MECHANICALLY VENTILATED patients in your ICU.
   - If the nurse to patient ratio for mechanically ventilated patients is not listed as an option, select '*Other'*.

2. Select the one most appropriate nurse to patient ratio (on average) for NON- MECHANICALLY VENTILATED patients in your ICU.
   - If the nurse to patient ratio for non-mechanically ventilated patients in your ICU is not listed as an option, select '*Other'*.

3. Select the one most appropriate range that includes the intensivist to patient ratio (on average) in your ICU during the day.
   - If the intensivist to patient ratio in your ICU is not listed as an option, select '*Other*'.

4. Select all of the staff, from the listed options, that regularly work in your ICU.

5. Select all appropriate senior clinical staff that provide out-of-hours clinical coverage during nights and weekends ON SITE in your ICU.
   - If your ICU does not have out-of-hours senior clinical coverage, select '*None of the above'.*
   - If the out-of-hours senior clinical coverage staff is not listed as an option, select '*Other*'.
   - If information on out-of-hours clinical coverage in your ICU is not known or available to you, select '*Unknown/Not available'*.

6. Select all appropriate specialty training of the intensivists working in your ICU.
   - If the specialty training of any intensivists working at your ICU is not listed as an option provided, select '*Other*'.

7. If respiratory therapists work in your ICU, select '*Yes'*.
   - If your ICU does not have respiratory therapists, select '*No'*.
   - If you are not aware if respiratory therapists work in your ICU, select '*Unknown/Not available'*.

8. If a dedicated pharmacist attends ICU rounds at least daily on weekdays, select '*Yes'*.
   - If there is no dedicated pharmacist attending daily ICU rounds, select '*No'*.
   - If you are not aware if a dedicated pharmacist attends daily ICU rounds, select '*Unknown/Not available'*.

9. If there is a dedicated physiotherapist at least daily on weekdays in your ICU, select '*Yes'*.
   - If there is no dedicated physiotherapist at least daily on weekdays, select '*No'*.
   - If you are not aware whether a dedicated physiotherapist works at least daily on weekdays, select '*Unknown/Not available'.*

10. If there is a mobility team in your ICU - with the primary role to mobilize the patient - select '*Yes'*.
    - If there is no mobility team available in your ICU, select '*No'*.
    - If you are not aware of a mobility team available in your ICU, select '*Unknown/Not available'*.

11. If a music therapist is available at your hospital, select '*Yes'*.
    - If there is no music therapist available at your hospital, select '*No'*.
    - If you are not aware of a music therapist available at your hospital, select '*Unknown/Not available'*.

12. If your hospital provides pet therapy or allows patients' pets to visit them in the ICU, select '*Yes'*.
    - If your hospital does not allow any pets in the ICU, select '*No'*.

- If information about pet therapy is not known or available, select '*Unknown/Not available'*.

13. Select all appropriate patient room structure(s) available in your ICU.

14. Select the one most appropriate visitor policy in place at your ICU.
    - If the visitor policy at your ICU is not listed as an option, select '*Other*'.

## C. ICU PRACTICES AND PROTOCOLS

1. Select all intravenous ANALGESICS available for use in your ICU.
    - If an intravenous analgesic available in your ICU is not listed as an option, select '*Other*'.

2. If a pain assessment scale is routinely used in your ICU, select '*Yes',* and proceed to Q 2.1.
    - If a pain assessment scale is not routinely used in your ICU, select '*No'*.
    - If availability or routine use of pain assessment scale at your ICU is not known or available, select '*Unknown/Not available'.*

    2.1 Select all pain assessment scale(s) that are routinely used in your ICU.
        - If a pain assessment scale at your ICU is not listed as an option, select '*Other'.*
        - If a pain assessment scale is routinely used, however, the name of the scale is not known or available, select '*Unknown/Not available'*.

3. Select all intravenous SEDATIVES available for use in your ICU.
    - If an intravenous sedative available in your ICU is not listed as an option, select '*Other*'.

4. If a sedation assessment scale is routinely used in your ICU, select '*Yes',* and proceed to Q 4.1.
    - If a sedation assessment scale is not routinely used in your ICU, select '*No'*.
    - If availability or routine use of a sedation assessment scale in your ICU is not known or available, select '*Unknown/Not available'.*

    4.1 Select all appropriate sedation assessment scale(s) that are routinely used in your ICU.
        - If a sedation assessment scale at your ICU is not listed as an (or in addition to) option, select '*Other'.*
        - If availability or routine use of sedation assessment scale at your ICU is not known or available, select '*Unknown/Not available'.*

5. If a delirium assessment scale is routinely used in your ICU, select '*Yes',* and proceed to Q 5.1.
    - If a delirium assessment scale is not routinely used in your ICU, select '*No'*.
    - If the routine use of a delirium assessment scale at your ICU is not known or not available, select '*Unknown/Not available'.*

    5.1 Select all delirium assessment scale(s) that are routinely used in your ICU.
        - If a delirium assessment scale at your ICU is not listed as an option, select '*Other'.*
        - If a delirium assessment scale is routinely used, however the name of the scale is not known or available, select '*Unknown/Not available'*.

6. Select all the staff personnel that evaluate patients for signs and symptoms of delirium in your ICU.
    - If the staff personal who evaluates patients for signs and symptoms of delirium in your ICU is not listed in (or in addition to) the options provided, select '*Other'*.
    - If your ICU does not assess patients for delirium, select '*Not Applicable - our ICU does not assess patients for delirium*'.

7. Select all protocols available for use in your ICU. A *protocol* (or algorithm) is a set of instructions or procedures for medical care of a specified clinical situation. Please do not confuse protocols with *clinical practice guidelines,* which are published documents designed to guide patient management in specific areas of healthcare.
   - If the protocol(s) in place at your ICU is/are not listed in the options provided, select '*None of the above*'.
   - If there are additional protocol(s) in place at your ICU, select all applicable protocols from the listed options AND select '*Other*'.
   - If information on protocols in place at your ICU is not known or available, select '*Unknown/Not applicable'.*

8. Select all routine patient management/interventions used in your ICU.
   - If the patient management/interventions routinely used in your ICU are not listed in the options provided, select '*None of the above*'.
   - If there are additional patient management/interventions routinely used in your ICU, select all appropriate managements/interventions from options provided AND select '*Other*'.
   - If information on routine patient management/interventions at your ICU is not known or available, select '*Unknown/Not available'.*

9. State the starting time of a day (in format of hh:mm), as per the ICU documentation, in your ICU.
   - For example, if your unit counts the day from the morning at 8:00 AM, input 08:00. If your unit counts the days from midnight, input 00:00.

**D. COVID-19**

1. Enter the date when there were at least 50 cases of COVID-19 confirmed or suspected that were admitted to your ICU in the format of DD/MM/YYYY.
   - If this information is not known or available, enter *'01/JAN/2001'*.

*2.* If a safety warning on shortage of sedative/analgesic/neuromuscular blocker drugs during the COVID-19 pandemic, select 'Yes' and proceed to Q2.1 and Q2.2
   - If no warning was issued on drug shortages or there was no drug shortage in your country, select '*No*'.
   - If information on issued warnings of drug shortages is not known or available, select '*Unknown/Not available*'.

   2.1 If a safety warning on drug shortages was issued at your hospital, please enter the date the warning was issued in the format of DD/MM/YYYY.
   2.2 If your hospital changed the sedation practice or drugs of choice for sedation after the safety warning was issued, select '*Yes*'.
      - If no changes to the sedation practice or drugs of choice for sedation was made after safety warning was issued, select '*No*'.
      - If information on changes in sedation practice or in drugs of choice for sedation is known or available, select '*Unknown/Not available*'.
   2.3 Select one of multiple drugs that were in short supply

3. If your ICU admitted any patients with COVID-19 diagnosis during the pandemic, select one of the following options and proceed to Q 3.1 and Q3.2 :

- Yes, we became a COVID-19 unit (admitted exclusively COVID-19 patients) during the pandemic surges, and did not expand our ICU bed capacity during the pandemic surges OR
- Yes, we became a COVID-19 unit (admitted exclusively COVID-19 patients) and expanded our ICU bed capacity during the pandemic surges OR
- Yes, we admitted both COVID-19 and non-COVID-19 patients during the pandemic surges

- If your ICU did not admit any patients with COVID-19 diagnosis during the pandemic, select one of the following options:
  - No, we did not admit COVID-19 patients, because we did not have COVID-19 critically ill patients in our centre/country OR
  - No, we did not admit COVID-19 patients, but we changed the type of patients admitted to our ICU (i.e., from specialist ICU to general ICU) OR
  - No, we did not admit COVID-19 patients, as they were diverted to dedicated COVID-19 units in our centre/country
- If information of COVID-19 patient admissions to your ICU is not known or available, select 'Unknown'
- If information of COVID-19 patient admissions to your ICU is different from the provided choices, select 'Other'.

Form 1: Site Demographics

3.1 Enter the date on which your first patient diagnosed with COVID-19 was admitted to your ICU in the format of DD/MMM/YYYY.
3.2 Select the one most appropriate reason for admission for the patient diagnosed with COVID-19 at your ICU.

- If the reason for admission of COVID-19 patient is not known or available, please state '*Unknown/Not available*'.

4. If there was no change in the cases admitted to your ICU before and during the pandemic (in other words, your ICU cared for the same group of patients before and during COVID-19), select 'Yes'.
   - If your ICU changed the case mix, and provided care for patients that they normally would not provide care for (prior to the COVID-19 pandemic), select 'No'.
   - If information of cases before and during the COVID-19 pandemic at your ICU is not known or available, select 'Unknown/Not available'.

5. Select all appropriate statements in the options provided in regards to the COVID-19 patients admitted to your ICU.

6. Select the one most appropriate nurse to patient ratio (on average) for MECHANICALLY VENTILATED patients in your ICU (please refer to practice DURING the COVID-19 pandemic surge) .
   - If the nurse to patient ratio for mechanically ventilated patients is not listed as an option, select '*Other*'.

7. Select the one most appropriate nurse to patient ratio (on average) for NON- MECHANICALLY VENTILATED patients in your ICU (please refer to practice DURING the COVID-19 pandemic surge).
   - If the nurse to patient ratio for non-mechanically ventilated patients in your ICU is not listed as an option, select '*Other*'.

8. Select the one most appropriate range that includes the intensivist to patient ratio (on average) in your ICU during the day (please refer to practice DURING the COVID-19 pandemic surge) .
   - If the intensivist to patient ratio in your ICU is not listed as an option, select '*Other*'.

9. Select all of the staff, from the listed options, that regularly work in your ICU (please refer to practice DURING the COVID-19 pandemic surge) .

10. Select all appropriate senior clinical staff that provide out-of-hours clinical coverage during nights and weekends ON SITE in your ICU (please refer to practice DURING the COVID-19 pandemic surge).

- If your ICU does not have out-of-hours senior clinical coverage, select '*None of the above'.*
- If the out-of-hours senior clinical coverage staff is not listed as an option, select '*Other*'.
- If information on out-of-hours clinical coverage in your ICU is not known or available to you, select '*Unknown/Not available'*.

11. Select all appropriate specialty training of the intensivists working in your ICU (please refer to practice DURING the COVID-19 pandemic surge).
    - If the specialty training of any intensivists working at your ICU is not listed as an option provided, select '*Other'*.
12. Select the one most appropriate visitor policy in place at your ICU (please refer to practice DURING the COVID-19 pandemic surge).
    - If the visitor policy at your ICU is not listed as an option, select 'Other'.



## FORM 2: PATIENT DEMOGRAPHICS AND OUTCOMES

### A. Admission

Please enter the date SAnDMAN Form 2 is completed in format of DD/MMM/YYYY, where MMM is entered in letters (e.g., SEP).

1. Enter the patient's age.

2. Select the patient's sex.
    - If patient does not identify as female or male, select '*Non-binary*'.
    - If patient's sex is not known or available, select '*Unknown/Not available'*.

3. Enter patient's weight (in kilograms) on admission.
    - If the patient's weight is not available, enter the weight as *'999 kg'*.

4. Enter the patient's date of ICU admission in the format of DD/MMM/YYYY.
    - If patient's date of ICU admission is not known or available, enter *'01/JAN/2001'*.

5. If the patient had a planned admission to the hospital (e.g., for a diagnostic or therapeutic procedure), select '*Elective/Planned'*.
    - If patient had an emergent or unplanned admission to the hospital, select '*Emergent/Unplanned'.*
    - If you are unaware of patient's admission history, select '*Unknown/not available'*.

6. Select the one most appropriate ICU admission type for the patient, then proceed to Q 6.1 or 6.2 or 6.3.

    6.1 If the type of ICU admission is '***Surgical'***, select one most fitting primary diagnosis.
    - If the patient's primary diagnosis is not listed in the options provided, select '*Other'*.
    - If the patient's primary diagnosis is not known or available, select '*Unknown/Not available'.*

    6.2 If the type of ICU admission is '***Medical'***, select one most fitting primary diagnosis.
    - If the patient's primary diagnosis is not listed in the options provided, please select '*Other'*.
    - If the patient's primary diagnosis is not known or available, select '*Unknown/Not available'.*

    6.3 If the type of ICU admission is '***Trauma'***, select one most fitting primary diagnosis.
    - If the patient's primary diagnosis is not listed in the options provided, please select '*Other'*.
    - If the patient's primary diagnosis is not known or available, select '*Unknown/Not available'.*

7. Please enter the most appropriate **primary** diagnosis at the time of the patient's admission to ICU.
    - If the admission diagnosis is not known or available, please state '*NA'*.

8. Please enter the most appropriate **secondary** diagnosis at the time of the patient's admission to ICU.
   - If the admission diagnosis is not known or available, please state '*NA'*.

## B. ICU ORGAN SUPPORT

1. Enter the date when the patient was intubated and mechanical ventilation (MV) was started, in the format of DD/MMM/YYYY.
   - If the date is not known, enter the date as '*01/JAN/2001'*.
   - Do not recruit patient in the study if patient is intubated and extubated in operating theatre prior to arrival to ICU as this does not fulfil SAnDMAN's inclusion criteria.
   - If patient is intubated in the operating theatre and extubated in ICU, enter the date of intubation regardless of the location.

2. Enter the date the patient was successfully extubated and MV was stopped in format of DD/MMM/YYYY.
   - Successful extubation is defined as ≥48 hours without requiring re-intubation.
   - If the patient was re-intubated within 48 hours of extubation – do **not** specify successful extubation or need for reintubation as this should be considered continuous days of mechanical ventilation.
   - If the date is not available or the patient was transferred to another location prior to extubation, enter the date as '*01/JAN/2001'.*
   - Please enter the most recent extubation date if the patient had more than one intubation during their ICU admission.
   - If patient is intubated in the operating theatre and extubated in ICU, enter the date of extubation in ICU.
   - If patient died while mechanically ventilated, enter the date of death.

3. If patient had a tracheostomy in the ICU, select '*Yes',* and proceed to following Q 3.1.
   - If patient did not undergo a tracheotomy procedure in the ICU, select '*No'*.
   - If patient underwent tracheotomy procedure, however, it is not known whether the procedure was performed during patient's current ICU stay, select '*Unknown/Not available'.*

   3.1 Enter the tracheostomy procedure date in format of DD/MMM/YYYY.
   - If the procedure date is not known or available, enter the date as '*01/JAN/2001'*.
   - If the patient is extubated to have a tracheostomy, the resulting date of extubation and of tracheostomy procedure should be the same.

   4. Enter Mechanical Ventilation liberation date in format of DD/MMM/YYYY
   - If the procedure date is not known or available, enter the date as '*01/JAN/2001'*.

5. If the patient received Renal Replacement Therapy (hemodialysis, peritoneal dialysis, or continuous renal replacement) during their ICU admission, select '*Yes'*.
   - If patient was not started on Renal Replacement Therapy in ICU, select '*No'*.
   - If you do not know whether the patient received Renal Replacement Therapy in ICU, select '*Unknown/Not available'*.

## C. DISCHARGE

1. State the patient's discharge date from the ICU in format of DD/MMM/YYYY.
   6. If the date is not available or known, enter the date as '*01/JAN/2001'*.
   7. If the patient is still in the ICU, enter the date as '08/AUG/2008'

- *The date of hospital discharge refers to patients who were successfully discharged for more than 48 hours. If the patient was readmitted to hospital within 48 hours, it is considered the same admission.*

2. Select the patient's status upon discharge from the ICU.
   - If patient was discharged from the ICU '*Alive*', proceed to Q 2.1, 2.2, and 2.3.
   - If patient died in the ICU, select '*Deceased*'.
   - If patient's status when discharged from ICU is not known or available, select '*Unknown/Not available'.*

   2.1. If the patient was discharged from the hospital '*Alive*', select the location the patient was discharged to from the ICU.
      - If patient was discharged from ICU directly to another hospital's ICU/HDU, select '*Another hospital (ICU/HDU)*'.
      - If patient was discharged from ICU directly to another hospital's general ward, select '*Another hospital (ward)*'.
      - If patient was discharged directly home from the ICU, select '*Home'.*
      - If patient was discharge to hospice care center, select '*Hospice*'.
      - If patient was transferred to a critical care step-down or high dependency unit, select '*Intermediate Care/High Dependency Unit'.*
      - If patient was discharged to a nursing home, select '*Nursing home*'.
      - If patient was discharge to a rehabilitation institution, select '*Rehabilitation*'.
      - If patient was transferred to a general ward, select '*Ward'.*
      - If patient was discharged to a destination or facility not listed in the options, select '*Other*'.
      - If the discharge disposition is not known or available, select '*Data/Information not available*'.

   2.2. If the patient was discharged from the ICU '*Alive',* enter the date patient was discharged from the hospital.
      - If the date is not known or available, state the date as '*01/JAN/2001'.*

   2.3. If patient was discharged from the ICU '*Alive',* select the patient's status upon discharge from the hospital.
      - If patient was alive upon ICU discharge but died in the hospital, select '*Deceased*'.
      - If patient's status when discharged from hospital is not known or available, select '*Unknown/Not available'*

## FORM 3: DAILY PATIENT DATA

Please enter the date SAnDMAN Case Report Form 3 is completed in format of DD/MMM/YYYY.

Study days are defined as calendar days. For example, if a patient is admitted on June 6th at 11:00, day 1 will be June 6th from 11:00- 23:59; and day 2 will be June 7th from 00:00-23:59.

### A. SOFA Score and Mechanical Ventilation

1. SOFA Score
   - For Glasgow Coma Scale select the **best** score of the day.
   - For the other physiologic variables, select the **worst** value in the day.
   - If no SOFA score parameter is not reported or not known, select '*Unknown/Not available'.*
   - For $PaO_2/FiO_2$ ratio: if an arterial blood gas was not done today, use the conversion table below to estimate the $PaO_2$.

Estimating $PaO_2$ from Saturation

| $SO_2$ (%) | $PaO_2$ (mmHg) |
|---|---|
| 80 | 44 |
| 81 | 45 |
| 82 | 46 |
| 83 | 47 |
| 84 | 49 |
| 85 | 50 |
| 86 | 52 |
| 87 | 53 |
| 88 | 55 |
| 89 | 57 |
| 90 | 60 |
| 91 | 62 |
| 92 | 65 |
| 93 | 69 |
| 94 | 73 |
| 95 | 79 |
| 96 | 86 |
| 97 | 96 |
| 98 | 112 |
| 99 | 145 |

Estimating $FiO_2$ From Nasal Cannula

| Method | $O_2$ flow (l/min) | Estimated FiO2 (%) |
|---|---|---|
| Nasel cannula | 1 | 24 |
| | 2 | 28 |
| | 3 | 32 |
| | 4 | 36 |
| | 5 | 40 |
| | 6 | 44 |
| Nasopharyngeal catheter | 4 | 40 |
| | 5 | 50 |
| | 6 | 60 |
| Face mask | 5 | 40 |
| | 6-7 | 50 |
| | 7-8 | 60 |
| Face mask with reservoir | 6 | 60 |
| | 7 | 70 |
| | 8 | 80 |
| | 9 | 90 |
| | 10 | 95 |

2. Select the <u>one</u> most appropriate mode of respiratory support that was applied for the majority of the day.
   - If patient was on a mode that is not listed in the options provided, select '*Other*'.
   - If the mode of respiratory support is not known or available, select '*Data/Information not available'.*

3. If prone positioning for hypoxaemia was required for a patient today, select '*Yes'* and proceed to Q 3.1.
   - If prone positioning was not required for patient, select '*No'*.
   - If information on prone positioning for patient is not known or available, select '*Unknown/Not Available'*.

   3.1. If patient required prone positioning for hypoxaemia, please enter the duration the patient was in the prone position.

### B. Sedation and Analgesia

1. If the patient received ANY SEDATIVE today (intravenous or enteral), select 'Yes' and proceed to Q 1.1 and 1.2.
   - If patient did not receive any sedation today, select '*No'.*
   - If you do not know whether the patient received ANY form of sedative today, select *'Unknown/Not available'.*

   1.1. If the patient received sedation today, select <u>all</u> of the indications for it.
   - If the indication for sedation is not listed as an option, select '*Other'.*
   - If the indication for sedation is not known, select '*Unknown/Not available'.*

   1.2. If the sedative was titrated to a scale (e.g. RASS or SAS), select '*Yes',* and proceed to Q 1.2.1 to 1.2.3.

- If the sedative was not titrated according to a scale, select '*No*'.
- If patient was given sedative, however, it is not known if the sedative was titrated according to a sedation scale, select '*Unknown/Not available'*.

1.2.1. Select **all** applicable scales used for sedative titration for the patient.
- If the sedative titration scale is not listed in the options provided, select '*Other'*.
- If patient was given a sedative, however, the name of the sedation scale is not known or available, select '*Unknown/Not available'.*

1.2.2. If the sedative was titrated according to a formal written protocol or algorithm, select '*Yes'*.
- If the sedative was not titrated according to a formal written protocol or algorithm, select '*No'.*
- If it is not known if the sedative was titrated according to a formal written protocol or algorithm, select '*Unknown/Not available'.*

1.2.3. If the sedative was titrated according to neuromonitoring, select the neuromonitoring method(s) from the options provided.
- If the sedative was not titrated according to neuromonitoring, select '*No neuromonitoring used'.*
- If the neuromonitoring method used is not listed among the options provided, select '*Other'.*
- If the patient was given a sedative, however, it is not known if the sedative was titrated according to neuromonitoring or the neuromonitoring method is not known, select '*Unknown/Not available'.*

2. If the patient received ANY ANALGESIC today, select 'Yes', and proceed to Q 2.1 to 2.3.
- If patient did not receive any analgesic today, select '*No'.*
- If you do not know whether the patient received ANY form of analgesic today, select *'Unknown/Not available'.*

2.1. If the analgesic was titrated according to a pain scale, select '*Yes',* and proceed to Q 2.1.1.
- If the analgesic was not titrated according to a pain scale, select '*No*'.
- If patient was given an analgesic, however, it is not known if the analgesic was titrated according to a pain scale, select '*Unknown/Not available'.*

2.1.1. If the analgesic was titrated according to a pain scale, select **all** applicable scales used for analgesic titration for the patient.
- If the pain scale used for analgesic titration for the patient is not listed in the options provided, select '*Other*'.
- If patient was given an analgesic, however the pain scale for analgesic titration is not known, select '*Unknown/Not available'.*

2.2. Target pain score refers to goal-directed delivery of analgesic medications to achieve a pain scale score (e.g. pain score 2 out of 10).
- If a target pain score was set for the patient today, select '*Yes'*.
- If a target pain score was not set for the patient today, select '*No'*.
- If patient received an analgesic, however, it is not known if a target pain score was set for the patient, select '*Unknown/Not available*'.

2.3. If the analgesia was titrated according to a formal written protocol or algorithm, select '*Yes'*.
- If analgesia was not titrated according to a formal written protocol, select '*No'.*

- If patient was given analgesia, however, it is not known if it was titrated according to a formal written protocol or algorithm, select '*Unknown/Not available'*

3. If the patient received a continuous infusion of SEDATIVE OR ANALGESIC today, select '*Yes'*, and proceed to Q 3.1 to 3.5.
   - If patient did not receive a continuous infusion of sedative OR analgesic today, select '*No'.*
   - If you do not know whether the patient received continuous infusion of sedative OR analgesic today, select *'Unknown/Not available'.*

3.1. If continuous SEDATIVE infusion was intentionally **interrupted** TODAY, select 'Yes' and proceed to Q 3.1.1.
   - If the sedative infusion was not interrupted today, select 'No'.
   - If the sedative infusion was interrupted, however, you do not know whether it was intentional or unintentional, select '*Unknown/Not available'*.

3.1.1. If ANY SEDATIVE infusion was interrupted and **restarted** TODAY, select '*Yes',* and proceed to Q 3.1.1.1.
   - If any sedative infusion was interrupted and NOT restarted today, select '*No'.*
   - If any sedative infusion was interrupted, however, you do not know if it was restarted today, select '*Unknown/Not Available'.*

   3.1.1.1. If the SEDATIVE infusion was restarted at the same **rate** as prior to the interruption, select 'At *previous rate/dose'*.
      - If the infusion was restarted at a lower rate, select '*LESS than the previous rate/dose'.*
      - If the infusion was restarted at a higher rate, select '*HIGHER than the previous rate/dose'.*
      - If the infusion was restarted, however you do not know if it was restarted at a higher or lower rate, select '*Unknown/Not available'.*

3.2. If continuous ANALGESIC infusion was intentionally **interrupted** TODAY, select '*Yes'*, and proceed to Q 3.2.1.
   - If the infusion was not interrupted today, select '*No'*.
   - If the infusion was interrupted, however, you do not know whether it was intentional or unintentional, select '*Unknown/Not available'*.

3.2.1. If ANY ANALGESIC infusion was interrupted and **restarted** TODAY, select '*Yes',* and proceed to Q 3.2.1.1.
   - If any analgesic infusion was interrupted and NOT restarted today, select '*No'.*
   - If any analgesic infusion was interrupted, however, you do not know if it was restarted today, select '*Unknown/Not Available'.*

   3.2.1.1. If the ANALGESIC infusion was restarted at the same **rate** as prior to the interruption, select 'At *previous rate/dose'.*
      - If the infusion was restarted at a lower rate, select '*LESS than the previous rate/dose'.*
      - If the infusion was restarted at a higher rate, select '*HIGHER than the previous rate/dose'.*
      - If the infusion was restarted, however, you do not know if it was restarted at a higher or lower rate, select '*Unknown/Not available'.*

3.3. Enter <u>all</u> sedative AND analgesic INFUSIONS administered to the patient today. Do NOT enter antipsychotics here.

- For **each** infusion administered today, enter the drug name, and the total dose of that drug administered over 24 hours, in milligrams (mg) (e.g. propofol, midazolam, lorazepam, morphine, hypdromorphone) or in micrograms (mcg) (e.g., dexmedetomidine, fentanyl, remifentanil). For each drug, enter the total number of hours of infusion the patient received during the 24-hour period.

- Examples of commonly used drugs are listed here. There may be others that are not listed – please enter them in the eCRF. Please note that drugs with '*' are usually in mcg dosing.

| | | |
|---|---|---|
| **Analgesics** | Non-Opioid Analgesics | Paracetamol/acetaminophen (Enteral or IV), Non-Steroidal Anti-Inflammatory Agents (NSAIDs) |
| | Opioids | alfentanil, codeine, meperidine, morphine, methadone, **fentanyl***, **remifentanil***, hydromorphone |
| **IV and Enteral Sedatives** | Benzodiazepines | midazolam, lorazepam, clonazepam, diazepam, temazepam, bromazepam, alprazolam |
| | Non-Benzodiazepines | clonidine, propranolol, etomidate, ketamine |
| | Hypnotics/Sleep Aids | melatonin, zopiclone, zolpidem, mirtazapine, trazadone |

3.4. Please determine whether the SEDATIVE infusion rate was different during the day-time (08:00-20:00) when compared to night-time (20:00-08:00).
- If there was no difference in rate of sedative infusion between day-time and night-time, select '*No difference*'.
- If rate of sedative infusion for either day-time or night-time is not available for comparison, select '*Unknown/Not available*'.

3.5. Please determine whether the ANALGESIC infusion rate was different during the day-time (08:00-20:00) when compared to night-time (20:00-08:00).
- If there was no difference in rate of analgesic infusion between day-time and night-time, select '*No difference*'.
- If rate of analgesic infusion for either day-time or night-time is not available for comparison, select '*Unknown/Not available*'

4. List **all** INTERMITTENT INTRAVENOUS sedative and analgesic medications administered to the patient today. Do **NOT** enter antipsychotics here.
- For each medication administered today, enter the total number of doses (between 1-100) given over 24 hours, and the total dose administered (between 1-4000 mg) with units over 24 hours. CONVERT ALL DOSES TO MILLIGRAMS (mg). (e.g., for Fentanyl 100 mcg = 0.1 mg).
- Examples of commonly used drugs are listed in the table below. There may be others that are not listed – please enter them in the eCRF. Please note that drugs with '*' are usually in mcg dosing and must be converted to mg (100 mcg = 0.1 mg).

| | | |
|---|---|---|
| **Analgesics (units)** | Non-Opioid Analgesics | Paracetamol/acetaminophen (Enteral or IV), Non-Steroidal Anti-Inflammatory Agents (NSAIDs) |
| | Opioids | Alfentanil, codeine, meperidine, morphine, methadone, **fentanyl***, **remifentanil***, sufentanil, hydromorphone |
| **IV and Enteral Sedatives (units)** | Benzodiazepines | midazolam, lorazepam, clonazepam, diazepam, temazepam, bromazepam, alprazolam |
| | Non-Benzodiazepines | Clonidine, propranolol, propofol, **dexmedetomidine***, etomidate, ketamine |
| | Hypnotics/Sleep Aids | melatonin, zopiclone, zolpidem, mirtazapine, trazadone |

5. List **all** ENTERAL sedative and analgesic medications (including sublingual) administered to the patient today. Do **NOT** enter antipsychotics here.
   - For each medication administered today, enter the number of doses (between 1-40) over 24 hours, and total dose administered (between 1-6000) with units (e.g.mg) over 24 hours. CONVERT ALL DOSES TO MILLIGRAMS (mg) (100 mcg = 0.1 mg).
   - Examples of commonly used drugs are listed in the table below. There may be others that are not listed – please enter them in the eCRF. Please note that drugs with '*' are usually in mcg dosing and must be converted to mg (100 mcg = 0.1 mg).

| | | |
|---|---|---|
| **Analgesics (units)** | Non-Opioid Analgesics | Paracetamol/acetaminophen (Enteral or IV), Non-Steroidal Anti-Inflammatory Agents (NSAIDs) |
| | Opioids | Alfentanil, codeine, meperidine, morphine, methadone, **fentanyl***, **remifentanil***, sufentanil, hydromorphone |
| **IV and Enteral Sedatives (units)** | Benzodiazepines | midazolam, lorazepam, clonazepam, diazepam, temazepam, bromazepam, alprazolam |
| | Non-Benzodiazepines | Clonidine, propranolol, propofol, **dexmedetomidine***, etomidate, ketamine |
| | Hypnotics/Sleep Aids | melatonin, zopiclone, zolpidem, mirtazapine, trazadone |

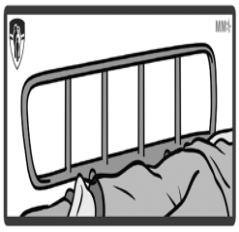
## C. Agitation and antipsychotics

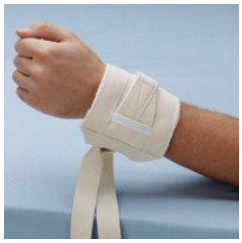
1. If any form of physical restraint was applied TODAY, select '*Yes*', and proceed to Q 1.1.
   - If no physical restraints were applied today, select '*No*'.
   - If it is unclear whether patient had restraints applied TODAY, select '*Unknown/Not available'.*

1.1. Select **all** types of physical restraint that were used on the patient. *See below for visual reference*.
   - If patient had physical restraints applied today, however, the type of restraint is not listed in the response options, select '*Other'.*
   - If patient was physically restrained, however, it is not known what type of physical restraint was used, select '*Unknown/Not available*'.


Hand Mitts


Torso Support



Bed Rail Restraints


Wrists


Belt Restraints


Lap Restraints


Belt in Chair

2. If the patient experienced accidental removal of any lines/catheters/tubes TODAY, select '*Yes*', and proceed to Q 2.1
   - If there was no accidental removal of any lines/catheters/tubes, select '*No'*.
   - If it is not known whether any lines/catheters/tubes were accidently removed by the patient today, or it is not clear if the incident occurred TODAY, select '*Unknown/Not available*'.

2.1. Select **all** devices that were accidentally removed TODAY.
   - If a device that was accidentally removed TODAY is not listed in the options provided, select '*Other'*.
   - If a device was accidentally removed, however, it is not known what type of device was accidentally removed, select '*Unknown/Not available'*.

3. Enter **all** atypical or typical antipsychotic agents administered (regular and as needed (PRN) orders) for prevention or treatment of agitation, combative behavior, or delirium.
   - For each medication administered today, enter the route of administration, number of doses (between 1-100) over 24 hours, and total dose administered (between 1-1000) over 24 hours with units (mg).
   - Examples of commonly used drugs are listed in the table below. There may be others that are not listed – please enter them in the eCRF.

| | |
|---|---|
| **Typical Antipsychotics (units)** | Chlorpromazine, flupenthixol, afluphenazine, haloperidol, loxapine, perphenazine, pimozide, trifluoperazine, thiothixene, zuclopenthixol |
| **Atypical Antipsychotics (units)** | Risperidone, quetiapine, olanzapine, ziprasidone, paliperidone, aripiprazole, clozapine |

4. If the patient was formally assessed for delirium TODAY, select '*Yes'*, and proceed to Q 4.1 and 4.2.
   - If the patient was not formally assessed for delirium TODAY, select '*No'*.
   - If it is not known whether the patient was assessed for delirium TODAY, select '*Unknown/Not available*'.

4.1. Select all applicable scales used to assess the patient for delirium today.
   - If a scale used for assessment of the patient for delirium is not listed as an option, select '*Other'*.
   - If the patient was assessed for delirium, however the assessment scale is not known, select '*Unknown/Not available'*

4.2. If the patient was diagnosed with delirium TODAY, select '*Yes'*, and proceed to Q 4.2.1 and 4.2.2.
   - If the patient was not diagnosed with delirium today, select '*No'*.
   - If it is not known whether the patient was diagnosed with delirium TODAY, select '*Unknown/Not available'*.

   4.2.1. Select the one most appropriate motor subtype of delirium that was prevalent today.
      - If the motor subtype of delirium is not known, select '*Unknown/Not available'*.

   4.2.2. Select all appropriate symptoms of delirium present in the patient today.
      - If a delirium symptom that was present today is not listed as an option, select '*Other'*.
      - If symptoms of delirium in the patient are not known, select '*Unknown/Not available*'.

## D. Neuromuscular Blockers

1. If patient received a neuromuscular blocking/paralytic agent today, select '*Yes*', and proceed to Q 1.1 to 1.4.
   - If the patient did not receive any neuromuscular blocking agent, select '*No'*.
   - If it is not known whether the patient received a neuromuscular agent today, select '*Unknown/Not Available'*.

1.1. Select all appropriate indications for paralysis of the patient.
- If the reason is not listed in the response options, select '*Other'.*
- If the reason is not known, select '*Unknown/Not available'.*

1.2. Select the one most appropriate mode of administration of the paralytic: intravenous bolus or continuous infusion.
- If the mode of administration was via **continuous infusion**, proceed to Q 1.2.1.
- If the administration route is not known, select '*Unknown/Not available.'*

1.2.1. If the continuous infusion of paralytic agent was **intentionally** interrupted today (for whatever reason), select '*Yes'*.
- If the paralytic agent was not intentionally interrupted today, select '*No'*.
- If the patient was receiving a paralytic agent today, but it's not known whether there was an interruption, please select '*Unknown/Not available'.*

1.3. Select all appropriate methods used for monitoring of the neuromuscular blocking agent today.
- If the method of monitoring neuromuscular blocking agent is not listed in the options provided, select '*Other*'.
- If it is not known whether the neuromuscular blocking agent was monitored TODAY, or how the neuromuscular blocking agent was monitored, select '*Unknown/Not available*'.

1.4. List all neuromuscular blocking agents (paralytics) administered today.
- For each medication, select the most appropriate route (intermittent bolus or continuous infusion), and enter the total dose administered to the patient over 24 hours with units (mg).

## E. Mobility

1. Please select the most appropriate category that reflects the patient's highest level of mobility today.
   - If the patient's level of mobility is not known, select *Response 8.*