



CYCLE RCT #142

Plate #015

Study Day

Patient ID 1 (site #) (patient #)

Coded Patient Initials F L

Date 2 0 (dd/mm/yyyy)

DAILY DATA (Form 4.1 of 4)

Day of the week M Tu W Th F Sa Su

1. Advanced life support strategies received today (check ALL that apply)

- 1. Airway Access
2. Mechanical Ventilation (MV)
3. Other Ventilation Strategy
4. Vasopressor / Inotrope infusions
5. Dialysis

2. Drugs (check ALL that apply)

- 1. Systemic corticosteroid
2. Opiates
3. Benzodiazepines
4. Propofol
5. Neuromuscular blockers

3. MODS score (record values closest to 0800)

Platelets (platelets/mL*10^-3) Creatinine (umol/L) Bilirubin (umol/L) PaO2/FiO2 PaO2(mmHg) FiO2(0.21-1.00) HR (BPM)
MAP (mmHg) CVP (mmHg) *Glasgow Coma Score

4. RASS and CAM-ICU (RASS and CAM-ICU to be taken at same time and closest to 0800)

SAS / VAMASS -> RASS Conversion Chart

1. RASS (-) (+) (0 - 5) Not done

Table with 2 rows (SAS, VAMASS) and 11 columns (1, 2, X, 3, X, 4, 5, 6, 7, X)

2. CAM-ICU Negative Positive Unable to Ax (RASS = -4 or -5) Scores >= 4 on Intensive Care Delirium Screening Checklist / ICDSC = CAM-ICU 'Positive'



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Date 2 0 (dd/mm/yyyy)

5. Nutrition

DAILY DATA (Form 4.2 of 4)

1. Enteral nutrition (EN) received today (check ONE type below; if >1 type received, select type providing the highest volume received)

No Yes → 24 hour total EN volume delivered (ml)

- Ensure High Protein (1.0 kcal/mL)
Ensure Plus Calories (1.5 kcal/mL)
Fibersource HN
Glucerna 1.0 kcal/mL + fibre
Impact Adv. Rec.
IsoSOURCE
IsoSOURCE HN 1.2
IsoSOURCE HN/Fiber 1.2 (+ fibre)
IsoSOURCE 1.5
IsoSOURCE 1.5/Fiber (+ fibre)
IsoSOURCE VHN/Fiber (1.0 kcal/mL + fibre)
IsoSOURCE VHP/1.0 HP (1.0 kcal/mL)
Jevity 1.0 Cal (+ fibre)
Jevity 1.2 Cal (+ fibre)
Jevity 1.5 Cal (+ fibre)
Nepro Carb Steady (1.8 kcal/mL + fibre)
Novosource Renal 2.0
Nutren 1.5
NutriHep (1.5 kcal/mL)
Nutrison 8000
Nutrison Protein Plus w/ Multifibre
Nutrison Concentrated
Novosource GI Forte
Novosource Renal 2.0
Optimental 1.0 kcal/mL
Osmolite
OXEPA (1.5 kcal/mL)
Peptamen 1.0
Peptamen 1.5
Peptamen AF 1.2 Cal (fish-oils and prebiotics)
Peptamen Intense
Promote (1.0 kcal/mL)
Resource 2.0
Resource Diabetic
TwoCal HN 2.0 (+ fibre)
Vital 1.0
Vital 1.5
Vital Peptide 1.5
Vivonex Plus
Vivonex T.E.N.

Other (specify) _____

2. Modular products received today? (check type(s), and record # packages received)

No Yes → Beneprotein Yes → # pkgs
Bramino Yes → # pkgs
EAS L-Glutamine Yes → # pkgs
Prosource Yes → # pkgs
Other (specify) Yes → # pkgs

3. Parenteral nutrition (PN) received today (record total PN volume received and macronutrients (specify units) received during 24 hour period)

No Yes → Volume (ml)
Dextrose (grams)
Amino Acid (grams)
Lipid (grams)

4. Oral intake received today?

No Yes → Oral (food) intake volume not required
 Oral (fluid) intake

5. Patient highest level of activity TODAY (including therapy sessions) [see Form 5, 5R, 5C; patient's chart (e.g. OT/PT/nursing notes)]

SCORE (0-11)

- 0 - Passively moved by staff (includes passive cycling only)
1 - Any activity in bed, but not moving out of or over edge of bed (includes cycling)
2 - Passively moved to chair (no standing or sitting at edge of bed)
3 - Actively sitting over side of bed with some trunk control (may be assisted)
4 - Standing
5 - Transferring from bed to chair
6 - Marching on the spot (at bedside; ≥ 2steps/foot)
7 - Walking with assistance of 2 or more people (≥5m)
8 - Walking with assistance of 1 person (≥5m)
9 - Walking independently with gait aid (≥5m)
10 - Walking independently without gait aid (≥5m)
11 - Walking up and down stairs

6. Is today a stat. holiday or weekend (i.e. ineligible day to offer and complete CYCLE trial intervention(s))

No Yes (no CYCLE Trial intervention today)
Did the patient receive any rehab therapy today from PT or OT? (check one; go to q 13)
 No Yes



CYCLE RCT #142

Plate #017

Study Day

Patient ID 1 (site #) (patient #)

Coded Patient Initials F L

Therapist(s) Initials F M L F M L

Date 20 (dd/mm/yyyy)

DAILY DATA (Form 4.3 of 4)

Day of week M Tu W Th F Sa Su

7. Was routine PT/ rehab done today?

- Yes (submit Form 5R)
No (check one of a, b, c, or d and specify where necessary)
a) Patient discharged from ICU before 1200pm
b) Temporary exemption criteria met (check ALL; if #10 specify)
1. Increase in inotropes/vasopressors (2h)
2. Active MI, or unstable/uncontrolled arrhythmia per ICU team
3. MAP <60 or >110 (2h) or out of range for this patient per ICU team
4. HR <40 or >140 (2h)
5. SpO2 <88% (2h) or out of range for this patient per ICU team
6. Neuromuscular blocker (4h)
7. Severe agitation RASS >2 or SAS >6 or equivalent (2h)
8. Uncontrolled pain
9. Changes in goals to palliative care
10. Other concern [e.g., active haemorrhage, acute peritonitis, new pelvic, groin, or extremity wound precluding routine PT/ rehab, new known or suspected muscle inflammation (specify below)]
c) Other reasons routine PT/rehab not received (check all that apply)
Refusals: Tired, Non-verbal behaviours indicating disinterest, Having a bad day, Other reason patient declined (specify), Family declined
Other activity prioritized by therapist: Cycling, Other (specify), Patient not scheduled for therapy
Therapist not available: Workload, Other (specify)
Patient not available: Out of ICU, While in ICU (procedure, test, etc.), Other (specify)
d) Other reason (specify)

8. Was cycling done today?

- N/A, patient not randomized to cycling
Yes (submit Form 5C)
No (check one of a, b, c, d, or e and specify where necessary)
a) Patient discharged from ICU before 1200pm
b) Patient marched on the spot for 2 consecutive days
c) Temporary exemption criteria met (check ALL; if #10 specify)
1. Increase in inotropes/vasopressors (2h)
2. Active MI, or unstable/uncontrolled arrhythmia per ICU team
3. MAP <60 or >110 (2h) or out of range for this patient per ICU team
4. HR <40 or >140 (2h)
5. SpO2 <88% (2h) or out of range for this patient per ICU team
6. Neuromuscular blocker (4h)
7. Severe agitation RASS >2 or SAS >6 or equivalent (2h)
8. Uncontrolled pain
9. Changes in goals to palliative care
10. Other concern [e.g., active haemorrhage, acute peritonitis, new pelvic, groin, or extremity wound precluding cycling, new known or suspected muscle inflammation (specify below)]
d) Other reasons cycling not received (check all that apply)
Refusals: Tired, Non-verbal behaviours indicating disinterest, Having a bad day, Other reason patient declined (specify), Family declined
Other activity prioritized by therapist: Other (specify)
Therapist not available: Workload, Other (specify), No CYCLE-trained therapist available
Patient not available: Out of ICU, While in ICU (procedure, test, etc.), Other (specify)
e) Other reason (specify)

9. Total # of screening attempts for cycling today? N/A (#)

10A. Therapy session duration (min)

- No PT/ rehab Session 1 (min)
N/A Session 2 (min)
N/A Session 3 (min)

10B. Therapy type(s) received

- Routine PT/ rehab Cycling
Routine PT/ rehab Cycling
Routine PT/ rehab Cycling

10C. Safety Events reported

- No Yes (complete Form 5S)
No Yes (complete Form 5S)
No Yes (complete Form 5S)

11. Patient highest level of activity from ALL rehabilitation/therapy sessions (includes Forms 5R, 5C, applicable S&F ax's)

- No PT/ rehab SCORE /5 (0-11)
0 - Passively moved by staff (includes passive cycling only)
1 - Any activity in bed, but not moving out of or over edge of bed (includes cycling)
2 - Passively moved to chair (no standing or sitting at edge of bed)
3 - Actively sitting over side of bed with some trunk control (may be assisted)
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12. Cognitive screening for ICU Awakening Ax: Strength and Function (Ask the patient to perform all 5 commands; check ALL successful commands)

- No PT/ rehab SCORE /5
Successful Commands: Open your eyes, Look at me, Open your mouth and stick out your tongue, Nod your head, Raise your eyebrows when I count to 5
Not done, patient unable to follow commands
No, score ≤2/5 (continue screening)
Yes, score ≥3/5 + not appropriate for PT ICU Awakening Ax (continue screening)
Yes, score ≥3/5 + appropriate for PT ICU Awakening Ax (initiate assessment)
Not done, PT ICU awakening Ax in progress/ complete



CYCLE RCT #142

Plate #018

Study Day

Patient ID 1
(site #) (patient #)

Coded Patient Initials
F L

Date 2 0
(dd/mm/yyyy)

DAILY DATA (Form 4.4 of 4)

13. Was the ICU Awakening: Strength and Function Form initiated today?

- No
- Yes (submit Form SF1)

14. Was the IPAT Form initiated today?

- No
- Yes (submit Form RC1)

15. Last day of study today?

- No, patient still within study day 28 protocol
- No, returned to ICU within 72 hours of ICU discharge
- Yes, patient discharged from the ICU >72 hours, died, or CYCLE RCT protocol stopped at 28 days (submit Forms: SF1-SF4, RC1-RC4, 6 and 7)
- Yes, consent withdrawn for further data collection (submit Form 7)

Who withdrew consent? (specify)

- Patient
- Legal SDM/ LAR
- Other family member
- Physician
- Other (specify) _____

Reason for Withdrawal? (specify) _____