



CYCLE RCT #142

Plate #001

Visit #000

Patient ID Coded Patient Initials
(site #) (patient type) (patient #)
1=randomized
2=eligible non-randomized
F L

Screening Date
(dd/mm/yyyy)

SCREENING (Form 1)

1. Inclusion Criteria (please tick the appropriate check-box)

1. Patient is ≥ 18 years of age
2. Patient is invasively mechanically ventilated ≤ 4 days
3. Expected additional 2 day ICU stay
4. Ability to ambulate independently (with or without gait aid) pre-hospital
5. ICU length of stay ≤ 7 days

	YES	NO
1.	Y <input type="checkbox"/>	N <input type="checkbox"/>
2.	Y <input type="checkbox"/>	N <input type="checkbox"/>
3.	Y <input type="checkbox"/>	N <input type="checkbox"/>
4.	Y <input type="checkbox"/>	N <input type="checkbox"/>
5.	Y <input type="checkbox"/>	N <input type="checkbox"/>

2. Exclusion Criteria

1. Pre-hospital inability to follow simple commands in local language at baseline
2. Acute conditions impairing ability to receive cycling (e.g., leg fracture)
3. Acute, proven, or suspected central or peripheral neuromuscular weakness (e.g., stroke, Guillian Barre)
4. Temporary pacemaker (internal or external)
5. Expected hospital mortality $\geq 90\%$
6. Equipment unable to fit patient's body dimensions (i.e., amputation, morbid obesity)
7. Palliative goals of care
8. Pregnancy
9. Specific surgical exclusion as stipulated by surgery team or ICU team

	YES	NO
1.	Y <input type="checkbox"/>	N <input type="checkbox"/>
2.	Y <input type="checkbox"/>	N <input type="checkbox"/>
3.	Y <input type="checkbox"/>	N <input type="checkbox"/>
4.	Y <input type="checkbox"/>	N <input type="checkbox"/>
5.	Y <input type="checkbox"/>	N <input type="checkbox"/>
6.	Y <input type="checkbox"/>	N <input type="checkbox"/>
7.	Y <input type="checkbox"/>	N <input type="checkbox"/>
8.	Y <input type="checkbox"/>	N <input type="checkbox"/>
9.	Y (specify) <input type="checkbox"/>	N <input type="checkbox"/>

10. Physician declines (i.e., severely impaired skin integrity, unstable in other ways)
(specify) _____

10.	Y (specify) <input type="checkbox"/>	N <input type="checkbox"/>
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11. Patient already able to march on the spot at time of screening

11.	Y <input type="checkbox"/>	N <input type="checkbox"/>
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12. Cycling Exemption not resolved during 1st 4 days of MV

Y (check all; specify if necessary)

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) _____

3. Study Eligible Non-Randomized Patients (enter into iDataFax)

1. Patient or SDM/ LAR declines consent
2. Patient unable to give consent and no SDM/ LAR identified
3. Physician declines patient or SDM/ LAR to be approached (specify) _____
4. Consent not obtained due to other reason (check ONE box only, for items a through f)

1.	Y <input type="checkbox"/>	N <input type="checkbox"/>
2.	Y <input type="checkbox"/>	N <input type="checkbox"/>
3.	Y <input type="checkbox"/>	N <input type="checkbox"/>
4.	Y <input type="checkbox"/>	N <input type="checkbox"/>

- FULL PT STAFF a. Insufficient PT resources and no CYCLE patients enrolled in ICU
- b. Insufficient PT resources because CYCLE patient(s) enrolled in ICU
- c. No PT available (off site, no PT around)
- ↓ PT STAFF d. Insufficient PT resources (e.g. randomization on hold → *only use after consulting with Methods Centre*)
- e. No RC available (off site, not available to screen)
- f. Other reason (specify) _____

5. Previously enrolled in this study (previous admit). Prior ID: _____

5.	Y <input type="checkbox"/>	N <input type="checkbox"/>
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4. Patient Status (check ONE box only)

Eligible, non-randomized

Included (go to Randomization Form 2)

5. Who provided consent? (check ONE box only)

Patient SDM/ LAR

6. Who obtained consent? (check ONE box only)

RC Site Investigator ICU MD



CYCLE RCT #142

Plate #005

Visit #000

Patient ID [] [] [1] [] []
(site #) (patient #)

Coded Patient Initials [] []
F L

RANDOMIZATION (Form 2)

FOR RESEARCH COORDINATOR

- 1. Age of patient ≥ 65 years
 ≤ 64 years

2. Date of birth [] [] [] [] [] [] [] []
(dd/mm/yyyy)

via web: www.randomize.net

Randomization Instructions

- a) Go to www.randomize.net
- b) Select "Account Login"
- c) Enter "Login ID" and "Password" (see Research Coordinator Binder); **do not change password**; if forgotten, contact Methods Centre
- d) Select "ENROLL A PATIENT"
- e) Select trial name "CYCLE RCT"
- f) Enter three-digit patient number to complete five-digit patient ID
(Note: three-digit patient number is randomization/enrolment #)

- 3. Study assignment (check one) **CYCLING + ROUTINE PT/ REHAB**
 ROUTINE PT/ REHAB

4. Date and local time of randomization [] [] [] [] [2] [0] [] [] Time [] [] : [] []
(dd/mm/yyyy) (24h - hr:min)

5. Date of consent [] [] [] [] [2] [0] [] []
(dd/mm/yyyy)

6. Initials of person who conducted the randomization [] []
F L

- 7. Who initially provided consent? (check one) **PATIENT LEGAL**
 SDM/LAR

- 8. Was consent provided for future data linkage? (check one) **Yes**
 No



CYCLE RCT #142

Plate #010

Visit #000

Patient ID [] [] [1] [] [] (site #) (patient #)

Coded Patient Initials [] [] F L

BASELINE (Form 3A.1 of 2)

TO BE COMPLETED AT THE TIME OF CONSENT WITH SDM/ LAR and/ or PATIENT

Instructions: Ask the patient or their SDM/ LAR the following regarding the patient's pre-hospital status

1. Pre-Hospitalization Employment Status (check ONE box that best describes the patient's pre-hospital employment status)

Part-time work, Full-time work, Retired, Disability, Unknown, Other (specify)

2. Pre-Hospitalization Living Status [before coming to the hospital, where was the patient living? (check ONE box)]

Home (independent), Home (with home care), Home (with unpaid caregiver assistance), Retirement Home (independent), Assisted Living Facility (mostly independent), Nursing Home/Long Term Care Facility, Chronic Care Facility/Complex Continuing Care Skilled Nursing Facility, Long Term Acute Care (LTAC), Inpatient Rehabilitation, Acute Care Hospital, Other (specify)

3. Pre-Hospitalization Marital Status (check ONE box)

Single, Married or Common law, Separated or Divorced, Other (specify)

4. Pre-Hospitalization Activities of Daily Living (ADL) (check ONE box per activity)

Table with 3 columns: ACTIVITY, INDEPENDENT, DEPENDENT. Rows include BATHING, DRESSING, GOING to the TOILET, TRANSFER, CONTINENCE, FEEDING.

5. Pre-Hospitalization Functional Status Score for ICU (please score each activity below from 0 - 7)

Rolling, Lie to sit, Sit @ edge of bed, Sit to stand, Bed to chair, *Walking. Scoring: 0 = Not able to perform, 1 = Total assistance, 2 = Maximal assistance, 3 = Moderate assistance, 4 = Minimal assistance, 5 = Supervision, 6 = Modified independence (device), 7 = Complete independence (timely and safely)

*Considerations for walking

*6 = Modified independence for walking [with device (e.g., cane walker, adapted shoe) ≥ 150 feet (~1/2 football field)]

*7 = Complete independence for walking (no device) ≥ 150 feet (~1/2 football field) in safe and timely manner



CYCLE RCT #142

Plate #011

Visit #000

Patient ID

(site #) (patient #)

Coded Patient Initials

F L

BASELINE (Form 3A.2 of 2)

TO BE COMPLETED AT THE TIME OF CONSENT WITH SDM/ LAR and/ or PATIENT

6. Pre-Hospitalization Admission Frailty Scale

Please record the participant's baseline health status from 2 weeks before ICU admission
 Considering the patient's pre-hospital admission status, please select the highest score from the descriptions below from 1 to 9.
 If the patient has characteristics from higher descriptors, then please report the highest score.

SCORE



1. **VERY FIT:** People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.



2. **WELL:** People who have **no active disease symptoms** but are less fit than category 1. Often, they exercise or are very **active occasionally**, e.g. seasonally



3. **MANAGING WELL:** People whose **medical problems are well controlled**, but are **not regularly active** beyond routine walking.



4. **VULNERABLE:** While **not dependent** on others for daily help, often **symptoms limit activities**. A common complaint is being "slowed up", and/or being tired during the day.



5. **MILDLY FRAIL:** These people often have **more evident slowing**, and need help in **high order IADLS** (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.



6. **MODERATELY FRAIL:** People who need help with **all outside activities** and with **keeping house**. Inside, they often have problems with stairs and need **help with bathing** and might need minimal assistance (cuing, standby) with dressing.



7. **SEVERELY FRAIL:** **Completely dependent for personal care**, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).



8. **VERY SEVERELY FRAIL:** Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness



9. **TERMINALLY ILL:** Approaching the end of life. This category applies to people with a **life expectancy <6 months**, who are **not otherwise evidently frail**.

Scoring frailty in people with dementia: The degree of frailty corresponds to the degree of dementia.

Common **symptoms in mild dementia** include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In **moderate dementia**, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In **severe dementia**, they cannot do personal care without help.

CYCLE RCT #142

Plate #012

Visit #000

Patient ID [] [] [1] [] [] (site #) (patient #)

Coded Patient Initials [] [] F L

BASELINE (Form 3B.1 of 2)

1. Study hospital admit date

[] [] [2] [0] [] []

2. Study ICU admit date and time

[] [] [2] [0] [] []

Time [] [] : [] []

3. Intubation date and time (most recent intubation prior to enrollment)

[] [] [2] [0] [] []

Time [] [] : [] [] (24h - hr:min)

4. Routine PT/rehab initial session assessment in ICU date

[] [] [2] [0] [] []

(dd/mm/yyyy)

5. Sex

Female Male

6. Height

[] [] [] cm inches

7. Actual weight (ICU admission)

[] [] [] kg lbs

Instructions: Calculate BMI; if > 30 kg/m², please check box "38F18" in "Co-morbid Disease" section on Baseline Form 3B.2
BMI(metric) = weight_kg / height²_m BMI(imperial) = weight_lbs / height²_inches X 703
Note: 1 kg = 2.2 lbs; 1 metre = 39.37 inches

8. Race/Ethnicity

White Hispanic or Latino Black or African American Indian (North or South)
 Asian (incl. Far East, SE Asia or Indian subcontinent) Other (specify) _____

9. Daily (24 hour) estimated total goal nutritional requirements (review dietician and/or nutritionist consults)

*Note: if reported as a RANGE of values, please use the LOWEST value of the given range

1. Energy (kcal, kJ or other)

No data [] [] [] [] (#) kcal kJ Other (specify) _____

2. Protein (grams or other)

No data [] [] [] (#) grams Other (specify) _____

10. APACHE II score

(first 24 hours in study ICU) [] [] (#)

11. APACHE III admission diagnosis code

[] [] (#) (If admitted from OR or PARR code should be 48-85; If "other" diagnosis code selected, specify)

12. Chronic Health Index from APACHE, (check ALL that apply)

1. Hepatic failure 4. Respiratory failure 7. Metastatic cancer (within 5 years) 10. AIDS 12. NONE (check one)
 2. Cirrhosis 5. Chronic dialysis (ESRD) 8. Leukemia 11. Other immunocompromise (chemotherapy, radiotherapy, alcoholism, recent high dose steroids ≥ 15 mg/kg for ≥ 5 days or steroids over last 30 days)
 3. Heart failure 6. Lymphoma 9. Multiple myeloma Check if HIV

13. Location immediately prior to this ICU admission (check ONE box):

Emergency Department Other hospital Emergency, admit date: [] [] [] [] [] []
 Hospital Floor/Ward (including step-down units) Other hospital ICU, admit date: [] [] [] [] [] []
 Operating Theatre /Recovery room (specify) Other hospital ward, admit date: [] [] [] [] [] []
 Emergency Surgery Elective Surgery Other (specify) _____
Other hospital/site admit date: [] [] [2] [0] [] [] (dd/mm/yyyy)



CYCLE RCT #142

Plate #013

Visit #000

Patient ID [] [] [1] [] [] []
(site #) (patient #)

Coded Patient Initials [] []
F L

BASELINE (Form 3B.2 of 2)

14. Co-morbid Disease - Charlson Comorbidity Index (C) & Functional Co-morbidity Index (F) (check ALL that apply)

* = Do not select more than one disease from these related consecutive diseases

Respiratory

- 1C **Chronic pulmonary disease** (incl asthma, COPD, home O₂)
- 2F3 Asthma - *also check 1C "Chronic pulmonary disease"*
- 3F4 Emphysema - *also check 1C "Chronic pulmonary disease"*
- 4F4 COPD (Chronic Obstructive Pulmonary Disease) - *also check 1C "Chronic pulmonary disease"*
- 5F4 Prior ARDS/ALI

Gastrointestinal

- 6F12 **Upper gastrointestinal disease** (incl ulcer, hernia, reflux/GERD)
- 7CF12 Peptic ulcer disease **ONLY** - *also check 6F12 "Upper GI disease"*

Neurological

- 8C Dementia (any, incl Alzheimer's, multi-infarct)
- 9F9 Stroke/CVA or TIA (*also check 11C "Hemiplegia..." if applicable*)
- 11C Hemiplegia or paraplegia
- 10F8 Neurologic (*any, incl MS, Parkinson's, uncontrolled seizures **excl.** CVA/TIA & Dementia*)

Endocrine

- 12CF11 *Diabetes **without** end organ damage
- 13CF11 *Diabetes **with** end organ (eye, nerve, or kidney) damage

Infectious Disease

- 14C *AIDS (No positive test for HIV/clinical diagnosis)
- 15C *AIDS (Known positive test for HIV)
- 16C *HIV (No evidence of AIDS)

Musculoskeletal

- 17F17 Degenerative disc disease (back dz, spinal stenosis or severe chronic back pain)

Mental Health

- 18F13 Depression
- 19F14 Anxiety or panic disorders

Cardiac and Vascular

- 20CF6 Congestive heart failure (CHF)
- 21F6 Heart disease (conditions affecting heart muscle, valves, or rhythm)
- 22CF7 Heart attack or Myocardial Infarction (MI)
- 23F5 Angina
- 24CF10 Peripheral vascular (PVD) (claudication, art. bypass, AAA>6cm)

Renal

- 25C *Kidney disease - *mild* (Creatinine 177 - 265 µmol/L)
- 26C *Kidney disease - *moderate or severe* (Creatinine > 265 µmol/L, dialysis, transplant)

Hematology/ Oncology

- 27C *Tumor (Solid, **with** metastatic disease)
- 28C *Tumor (Solid, **without** metastatic disease) (*within past 5 years*)
- 29C Leukemia (incl AML, CML, ALL, CLL, polycythemia vera)
- 30C Lymphoma (incl Hodgkin's & non-Hodgkins, lymphosarcoma, and myeloma)

Hepatic

- 31C *Liver disease - *mild* (Hep B or C, or cirrhosis w/o portal HTN)
- 32C *Liver disease - *moderate or severe* (varices, ascites, encephalopathy)

Connective Tissue/ Rheumatologic

- 33F2 Osteoporosis
- 34C Connective tissue disease - rheumatoid arthritis **ONLY**, or lupus/SLE, myositis
- 35F1 Arthritis - rheumatoid or osteoarthritis (*also check above options where applicable*)

Other

- 36F15 Visual impairment (e.g., cataracts, glaucoma, macular degeneration)
- 37F16 Hearing impairment (can't hear conversation even with hearing aids, if any)
- 38F18 Obesity and/or body mass index > 30kg/m²
Refer to Form 3B.1 BMI calculations; check box if necessary
- 39 **NONE**



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 No Yes → ETT Tracheostomy
- 2. Mechanical Ventilation (MV) No → None/Spontaneous (e.g. t-mask, venti-mask, nasal prongs)
 Yes → Invasive MV (e.g. pressure assist control, volume assist control, pressure support)
 Non-Invasive MV (e.g. BIPAP, CPAP by mask not ETT or trach, e.g., nocturnal)
- 3. Other Ventilation Strategy No Yes → ECMO/ECLS Nitric oxide High-flow nasal cannula (e.g. AIRVO, Optiflow)
 Other (specify) _____
- 4. Vasopressor / Inotrope infusions No Yes
(e.g., dopamine, norepinephrine, phenylephrine, epinephrine, milrinone, vasopressin)
- 5. Dialysis No Yes → Intermittent (IHD) Continuous (CRRT) Peritoneal Sustained low efficiency (SLED)
 Other (specify) _____

2. Drugs (check ALL that apply)

- 1. Systemic corticosteroid No Yes → Dexamethasone Methylprednisolone Hydrocortisone Prednisone
→ TOTAL DAILY DOSE (mg) Other (specify) _____
- 2. Opiates No Yes → Infusion Bolus Other route (specify) _____
(e.g., Fentanyl, Remifentanyl, Hydromorphone, Morphine, Oxycodone, Demerol, (Percocet), Codeine (Tylenol #1, 2, or 3), etc.)
- 3. Benzodiazepines No Yes → Infusion Bolus Other route (specify) _____
(e.g., Midazolam (Versed), Lorazepam (Ativan), Clonazepam, Diazepam, etc.)
- 4. Propofol No Yes → Infusion Bolus
- 5. Neuromuscular blockers No Yes → Infusion Bolus
(e.g., Cisatracurium, Rocuronium, Vecuronium, Atracurium, Pancuronium, Succinylcholine, etc.)

3. MODS score (record values closest to 0800)

Platelets (platelets/mL*10⁻³)
N/A

Creatinine (μmol/L)
N/A

Bilirubin (μmol/L)
N/A

PaO₂/FiO₂ OR /
N/A

PaO₂(mmHg) / FiO₂(0.21-1.00)
N/A

HR (BPM)
N/A

MAP (mmHg)
N/A

CVP (mmHg)
N/A

*Glasgow Coma Score (3 - 15 OR *3T-11T) Receiving sedation/opioids/NMB's when GCS reported?
 Not recorded *GCS verbal component = "T" (T = "1" included in GCS #)

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 (+)

SAS	1	2	X	3	X	4	5	6	7	X
RASS	-5	-4	-3	-2	-1	0	1	2	3	4
VAMASS	0	X	1	2	X	3	4	5	6	X

2. CAM-ICU Negative Positive Unable to Ax (RASS = -4 or -5)
 Not done

*Scores ≥ 4 on Intensive Care Delirium Screening Checklist / ICDSC = CAM-ICU "Positive"



CYCLE RCT #142

Plate #016

Study Day

Patient ID 1 (site #) (patient #)

Coded Patient Initials F L

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)
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

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
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
SCORE /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) _____



CYCLE RCT #142

Plate #020

Study Day

Patient ID 1
(site #) (patient #)

Coded Patient Initials
F L

Date 2 0
(dd/mm/yyyy)

DAILY DATA (Form 4A)

If a patient is **discharged from ICU and readmitted within 72 hours**, complete this form **in place of DAILY DATA (Form 4)** for each complete study day outside ICU prior to readmission.

1. Did the patient receive any physiotherapy/ rehabilitation therapy while outside ICU today?

No
 Yes

Day of week
M Tu W Th F Sa Su

2. Patient highest level of activity outside of ICU today?

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; ≥ 2 steps/foot)
- 7 - Walking with assistance of 2 or more people (≥ 5 m)
- 8 - Walking with assistance of 1 person (≥ 5 m)
- 9 - Walking independently with gait aid (≥ 5 m)
- 10 - Walking independently without gait aid (≥ 5 m)
- 11 - Walking up and down stairs



CYCLE RCT #142

Plate #021

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)

PT THERAPY: WORKSHEET (Form 5)

Day of week (M Tu W Th F Sa Su)

1. 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)

2. 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)

3. Total # of screening attempts for cycling today?

N/A (#)

4A. Therapy session duration (min)

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

4B. Therapy type(s) received

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

4C. Safety Events reported

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

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

- No PT/rehab
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. 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 #025

Study Day

Patient ID (site #) 1 (patient #)

Coded Patient Initials F L

Therapist(s) Initials F M L F M L

Date 2 0 (dd/mm/yyyy)

PT THERAPY: ROUTINE PT/ REHAB (Form 5R)

Complete form if patient receives any routine therapy (incl. therapy received while cycling)

Day of week M Tu W Th F Sa Su

1. Pre-routine therapy assessments SAS / VAMASS -> RASS Conversion Chart

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

RASS Conversion Chart table with columns SAS, RASS, VAMASS and rows 1-7

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

2. Vitals: highest O2 % received [21% (room air) - 100%] Session 1: (%) Session 2: (%) Session 3: (%)

3. ALL advanced life support strategies received DURING ANY ROUTINE PT/REHAB today (check ALL that apply)

- 1. Airway Access No Yes -> ETT Tracheostomy
2. Mechanical Ventilation (MV) No Yes -> Invasive MV Non-Invasive MV
3. Other Ventilation Strategy No Yes -> ECMO/ECLS Nitric oxide High-flow nasal cannula Other (specify)
4. Vasopressor / Inotrope infusions No Yes
5. Dialysis No Yes -> Intermittent (IHD) Continuous (CRRT) Peritoneal Sustained low efficiency (SLED) Other (specify)
6. Femoral Catheter in Situ No Yes -> Venous Arterial Other (specify)

4. Routine PT (usual care) rehabilitation activities (check ALL received)

1. Target: Independent airway clearance

Table for Target 1: Independent airway clearance with columns: Complete?, Physical Assistance (Percussion, Vibration, Rib springs, Suctioning), Instructions, Repetition, Feedback, Cues, Encouragement, Equipment (specify)

2. Target: Increase active ROM of limbs

Table for Target 2: Increase active ROM of limbs with columns: Complete?, Phys. Assist. (PROM, AAROM), Instructions, Repetition, Feedback, Cues, Encouragement, Motivation, Equipment (specify)

3. Target: Increase muscle strength

Table for Target 3: Increase muscle strength with columns: Complete?, Physical Resistance (Therapist, Bands, Weights), Instructions, Repetition, Feedback, Cues, Encouragement, Motivation, Equipment (specify)

4. Target: Independent transfers

Table for Target 4: Independent transfers with columns: Complete?, Physical Assistance (People) (None, Ax1, Ax2, >Ax2), Instructions, Repetition, Feedback, Cues, Encouragement, Motivation, Equipment (specify)

5. Target: Walking

Table for Target 5: Walking with columns: Complete?, Physical Assistance (People) (None, Ax1, Ax2, >Ax2), Instructions, Repetition, Feedback, Cues, Encouragement, Motivation, Equipment (specify)

5. Any safety events during routine PT/ rehab?

**stop session if any of these events occur: suspected new unstable/ uncontrolled arrhythmia, concern for MI, cardiac arrest, unplanned extubation, fall to knees No Yes (complete Safety Events Form 5S)

Comments



CYCLE RCT #142

Plate #030

Study Day

Patient ID 1 (site #) (patient #)

Coded Patient Initials F L

Therapist(s) Initials F M L F M L

Date 2 0 (dd/mm/yyyy)

RT 300 ID

RT 300 PIN

PT THERAPY: CYCLING (Form 5C)

Day of week M Tu W Th F Sa Su

1. Cycling session start time (equipment prepped and enter room)

: (24h-hr:min)

2. Pre-cycling therapy assessments

SAS / VAMASS → RASS Conversion Chart

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

SAS	1	2	X	3	X	4	5	6	7	X
RASS	-5	-4	-3	-2	-1	0	1	2	3	4
VAMASS	0	X	1	2	X	3	4	5	6	X

2. CAM-ICU Negative
 Not done Positive
 Unable to Ax (RASS = -4 or -5)
*Scores ≥ 4 on Intensive Care Delirium Screening Checklist / ICDSC = CAM-ICU "Positive"

3. Vitals: Highest O₂ % received (%)
[21% (room air) - 100%]

4. ALL advanced life support strategies received DURING CYCLING today (check ALL that apply)

- Airway Access No Yes → ETT Tracheostomy
- Mechanical Ventilation (MV) No → None/Spontaneous (e.g. t-mask, venti-mask, nasal prongs)
 Yes → Invasive MV (e.g. pressure assist control, volume assist control, pressure support)
 Non-Invasive MV (e.g. BIPAP, CPAP by mask not ETT or trach, e.g., nocturnal)
- Other Ventilation Strategy No Yes → ECMO/ECLS Nitric oxide High-flow nasal cannula Other (specify)
- Vasopressor / Inotrope infusions (e.g., dopamine, norepinephrine, phenylephrine, epinephrine, milrinone, vasopressin) No Yes
- Dialysis No Yes → Intermittent (IHD) Continuous (CRRT) Peritoneal Sustained low efficiency (SLED) Other (specify)
- Femoral Catheter in Situ No Yes → Venous Arterial Other (specify)

5. CYCLING THERAPY

Session Duration (MIN, tablet; check all that apply)	Mode (Active, Passive)	Pedal Spd. (RPM)	Power (Watts)	Any active cycling	<input type="checkbox"/> Yes <input type="checkbox"/> No
5 <input type="checkbox"/> >0 and ≤5 mins	<input type="checkbox"/> A <input type="checkbox"/> P	<input type="text"/>	<input type="text"/>	Distance travelled (Bike Tablet)	<input type="text"/> <input type="text"/> (km)
10 <input type="checkbox"/> >5 and ≤10 mins	<input type="checkbox"/> A <input type="checkbox"/> P	<input type="text"/>	<input type="text"/>	Total therapy time (Bike Tablet)	<input type="text"/> : <input type="text"/> (min:sec)
20 <input type="checkbox"/> >10 and ≤20 mins	<input type="checkbox"/> A <input type="checkbox"/> P	<input type="text"/>	<input type="text"/>	Time active (off motor) (Bike Tablet)	<input type="checkbox"/> N/A <input type="text"/> : <input type="text"/> (min:sec)
				Time passive (on motor) (Bike Tablet)	<input type="checkbox"/> N/A <input type="text"/> : <input type="text"/> (min:sec)

6. Did cycling finish before 30 minutes? No Yes (check ALL that apply)

- Patient's request Tired Other (specify) _____
- Therapist stopped session Agitation Cardiovascular (specify) _____ Respiratory (specify) _____ Other (specify) _____
- Physician stopped session (specify) _____
- Other (specify) _____

7. Any safety events during cycling therapy?

**stop session if any of these events occur: suspected new unstable/ uncontrolled arrhythmia, concern for MI, cardiac arrest, unplanned extubation
 No Yes (complete Safety Events Form 5S)

8. Cycling session end time (bike take down complete and end of cycling therapy portion of therapy session)

: (24h-hr:min)

Comments _____



CYCLE RCT #142

Plate #035

Study Day

Patient ID 1
(site #) (patient #)

Coded Patient Initials
F L

Date 2 0
(dd/mm/yyyy)

SAFETY EVENTS (Form 5S)

Complete this form if any safety events occurred during cycling or routine PT/ rehab

Cycling therapy safety events - Did any of the following occur during cycling therapy? (check ALL that apply)

** = stop session if any of these events occur

1. **Suspected new unstable/ uncontrolled arrhythmia
2. **Concern for myocardial ischaemia
3. **Cardiac Arrest
4. **Unplanned extubation
5. Bleeding at femoral catheter site attributed to in-bed cycling
6. New bruising at femoral catheter site attributed to in-bed cycling
7. Sustained O₂ desaturation below baseline and clinical deterioration attributed to in-bed cycling
8. Sustained symptomatic bradycardia (<40 bpm) or tachycardia (>140 bpm) and clinical deterioration attributed to in-bed cycling
9. Sustained hypertension (mean arterial pressure >120 mmHg) and clinical deterioration attributed to in-bed cycling
10. Removal or dysfunction of intravascular catheter (e.g., central venous catheter, arterial line, dialysis catheter) attributed to in-bed cycling
11. Other (specify) _____
12. What were the consequences of the safety event(s)?
 - None
 - Cycling therapy stopped
 - Other (specify) _____

Routine PT/rehab safety events - Did any of the following occur during routine PT/ rehab? (check ALL that apply)

** = stop session if any of these events occur

1. **Suspected new unstable/ uncontrolled arrhythmia
2. **Concern for myocardial ischaemia
3. **Cardiac Arrest
4. **Unplanned extubation
5. **Fall to knees
6. Bleeding at femoral catheter site attributed to routine PT/ rehab activities
7. New bruising at femoral catheter site attributed to routine PT/ rehab activities
8. Sustained O₂ desaturation below baseline and clinical deterioration attributed to routine PT/ rehab activities
9. Sustained symptomatic bradycardia (<40 bpm) or tachycardia (>140 bpm) and clinical deterioration attributed to routine PT/ rehab activities
10. Sustained hypertension (mean arterial pressure >120 mmHg) and clinical deterioration attributed to routine PT/ rehab activities
11. Removal or dysfunction of intravascular catheter (e.g., central venous catheter, arterial line, dialysis catheter) attributed to routine PT/ rehab activities
12. Other (specify) _____
13. What were the consequences of the safety event(s)?
 - None
 - Routine PT/ rehab stopped
 - Other (specify) _____

CYCLE RCT #142

Plate #041

Visit #040

Patient ID 1 Coded Patient Initials F L Therapist(s) Initials F M L F M L Test Date 2 0 (dd/mm/yyyy)

STRENGTH AND FUNCTION ASSESSMENT: ICU AWAKENING (SF1)

Reason # not done

- 1. Assessment (ax) merged with other ax form/ other timepoint (complete q# 1B)
- 2. Patient did not pass cog. screen. prior to ICU discharge (alive @ discharge)
- 3. Patient died prior to reaching timepoint
- 4. Goals of care changed to palliative
- 5. Patient or Proxy refusal
- 6. Assessment missed
- 7. Cognitive issue - patient too sedated/ agitated
- 8. Cognitive issue - patient unable to follow commands
- 9. Assessor perceives patient unable to perform due to safety concerns (e.g. physiological or physical)
- 10. Assessor perceives that patient is likely able to but has a limitation such as pain, lines, amputation, fatigue etc.
- 11. Other assessment prioritized
- 12. Other (specify)

1A. Any part of assessment completed/ any clinical data

Yes (go to 1B)
 No (insert reason # not done, if "other", specify) →
 (specify) _____

1B. Clinical data should apply to the following timepoints (check all)

ICU Awakening	ICU Discharge	3 D Post-ICU Discharge	Hospital Discharge
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. STRENGTH (MMT) → Assessor blinded? Yes No

Reason # not done (specify) _____

MUSCLE	RIGHT		LEFT		MUSCLE	RIGHT		LEFT	
	SCORE	Reason # not done	SCORE	Reason # not done		SCORE	Reason # not done	SCORE	Reason # not done
1. Shoulder Flexion^P	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>	5. Hip Flexion	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>
2. Shoulder Abduction	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>	6. Knee Extension^P	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>
3. Elbow Flexion	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>	7. Ankle Dorsiflexion	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>
4. Wrist Extension	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>					

3. SIT TO STAND: ASSISTANCE REQUIRED^P → Assessor blinded? Yes No

Reason # not done (specify) _____

1. **Level of assistance required^P** 0 people 1 person 2 people (or more) Attempted + unable
 2. Location Bed Chair → Armrest used? Yes No

4. MARCHING ON THE SPOT: CADENCE^P → Assessor blinded? Yes No

Reason # not done (specify) _____

1. Steps (#) Attempted + unable (if checked, insert score = "0" in "steps")

2. Time : = (seconds)

3. **Cadence^P** (steps/min)

$$\text{Cadence} = \frac{\text{Steps (\#)}}{\text{Time (seconds)}} \times 60$$

Marching on the spot instructions
 "Once you are in the standing position, we will ask you to march on the spot. We would like you to march on the spot for as long as you can. We are going to record how long you walk for and how many steps you do. The test is designed to record your maximum exercise ability, so it is very important that you march on the spot for as long as you possibly can."
 Give standardized encouragement every 10 seconds: "Keep going for as long as you can", "You're doing very well", "Well done". If applicable (ie retest), then: "Last time you performed the test, you marched for . . . and did . . . steps."

5. 30 SECOND SIT TO STAND → Assessor blinded? Yes No

Reason # not done (specify) _____

1. Sit to stand repetitions completed (#) Attempted + unable (if checked, insert score = "0" in "sit to stand repetitions completed")
 2. Level of assistance required 0 people 1 person 2 people (or more)
 3. Location Bed Chair → Armrest used? Yes No

Comments _____



CYCLE RCT #142

Plate #042

Visit #040

Patient ID **1** (site #) (patient #) Coded Patient Initials F L Therapist(s) Initials F M L F M L Test Date **20** (dd/mm/yyyy)

STRENGTH AND FUNCTION ASSESSMENT: ICU DISCHARGE (SF2)

Reason # not done

- 1. Assessment (ax) merged with other ax form/ other timepoint (complete q# 1B)
- 2. Patient did not pass cog. screen. prior to ICU discharge (alive @ discharge)
- 3. Patient died prior to reaching timepoint
- 4. Goals of care changed to palliative
- 5. Patient or Proxy refusal
- 6. Assessment missed
- 7. Cognitive issue - patient too sedated/ agitated
- 8. Cognitive issue - patient unable to follow commands
- 9. Assessor perceives patient unable to perform due to safety concerns (e.g. physiological or physical)
- 10. Assessor perceives that patient is likely able to but has a limitation such as pain, lines, amputation, fatigue etc.
- 11. Other assessment prioritized
- 12. Other (specify)

1A. Any part of assessment completed/ any clinical data

Yes (go to 1B)
 No (insert reason # not done, if "other", specify) →
 (specify) _____

1B. Clinical data should apply to the following timepoints (check all)

ICU Awakening ICU Discharge 3 D Post-ICU Discharge Hospital Discharge

2. STRENGTH (MMT) → Assessor blinded? Yes No

Reason # not done (specify) _____

MUSCLE	RIGHT		LEFT		MUSCLE	RIGHT		LEFT	
	SCORE	Reason # not done	SCORE	Reason # not done		SCORE	Reason # not done	SCORE	Reason # not done
1. Shoulder Flexion^P	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>	5. Hip Flexion	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>
2. Shoulder Abduction	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>	6. Knee Extension^P	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>
3. Elbow Flexion	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>	7. Ankle Dorsiflexion	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>
4. Wrist Extension	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>					

3. SIT TO STAND: ASSISTANCE REQUIRED^P → Assessor blinded? Yes No

Reason # not done (specify) _____

1. **Level of assistance required^P** 0 people 1 person 2 people (or more) Attempted + unable
 2. Location Bed Chair → Armrest used? Yes No

4. MARCHING ON THE SPOT: CADENCE^P → Assessor blinded? Yes No

Reason # not done (specify) _____

1. Steps (#) Attempted + unable (if checked, insert score = "0" in "steps")

2. Time : = (mm : sec) (seconds)

3. **Cadence^P** (steps/min)

$$\text{Cadence} = \frac{\text{Steps (\#)}}{\text{Time (seconds)}} \times 60$$

Marching on the spot instructions
 "Once you are in the standing position, we will ask you to march on the spot. We would like you to march on the spot for as long as you can. We are going to record how long you walk for and how many steps you do. The test is designed to record your maximum exercise ability, so it is very important that you march on the spot for as long as you possibly can."
 Give standardized encouragement every 10 seconds: "Keep going for as long as you can", "You're doing very well", "Well done". If applicable (ie retest), then: "Last time you performed the test, you marched for . . . and did . . . steps."

5. 30 SECOND SIT TO STAND → Assessor blinded? Yes No

Reason # not done (specify) _____

1. Sit to stand repetitions completed (#) Attempted + unable (if checked, insert score = "0" in "sit to stand repetitions completed")
 2. Level of assistance required 0 people 1 person 2 people (or more)
 3. Location Bed Chair → Armrest used? Yes No

6. 2 MINUTE WALK TEST → Assessor blinded? Yes No

Reason # not done (specify) _____

1. Distance OR Attempted + unable (if checked, insert score = "0" in "distance")
(1 metre = 3.28 feet) (metres) (feet)

2. Level of assistance required 0 people 1 person 2 people (or more)

3. Gait aid used [#, 1 = None, 2 = Cane or crutches, 3 = Walker, 4 = Other (specify)] (specify) _____

Comments _____



CYCLE RCT #142

Plate #043

Visit #040

Patient ID 1 (site #) (patient #)

Coded Patient Initials Therapist(s) Initials (F L) (F M L) (F M L)

Test Date 2 0 (dd/mm/yyyy)

STRENGTH AND FUNCTION ASSESSMENT: 3 DAYS POST-ICU DISCHARGE (SF3)

- | | |
|---------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| Reason # not done | |
| 1. Assessment (ax) merged with other ax form/ other timepoint (complete q# 1B) | 8. Cognitive issue - patient unable to follow commands |
| 2. Patient did not pass cog. screen. prior to ICU discharge (alive @ discharge) | 9. Assessor perceives patient unable to perform due to safety concerns (e.g. physiological or physical) |
| 3. Patient died prior to reaching timepoint | 10. Assessor perceives that patient is likely able to but has a limitation such as pain, lines, amputation, fatigue etc. |
| 4. Goals of care changed to palliative | 11. Other assessment prioritized |
| 5. Patient or Proxy refusal | 12. Other (specify) |
| 6. Assessment missed | |
| 7. Cognitive issue - patient too sedated/agitated | |

1A. Any part of assessment completed/ any clinical data

Yes (go to 1B)

No (insert reason # not done, if "other", specify) →

(specify) _____

1B. Clinical data should apply to the following timepoints (check all)

ICU Awakening	ICU Discharge	3 D Post-ICU Discharge	Hospital Discharge
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. STRENGTH (MMT) → Assessor blinded? Yes No

Reason # not done (specify) _____

MUSCLE	RIGHT		LEFT		MUSCLE	RIGHT		LEFT	
	SCORE	Reason # not done	SCORE	Reason # not done		SCORE	Reason # not done	SCORE	Reason # not done
1. Shoulder Flexion ^P	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>	5. Hip Flexion	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>
2. Shoulder Abduction	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>	6. Knee Extension ^P	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>
3. Elbow Flexion	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>	7. Ankle Dorsiflexion	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>
4. Wrist Extension	<input type="text"/> /5	<input type="text"/>	<input type="text"/> /5	<input type="text"/>					

3. SIT TO STAND: ASSISTANCE REQUIRED^P → Assessor blinded? Yes No

Reason # not done (specify) _____

1. Level of assistance required^P 0 people 1 person 2 people (or more) Attempted + unable

2. Location Bed Chair → Armrest used? Yes No

4. MARCHING ON THE SPOT: CADENCE^P → Assessor blinded? Yes No

Reason # not done (specify) _____

1. Steps (#) Attempted + unable (if checked, insert score = "0" in "steps")

2. Time : = (mm : sec) (seconds)

3. **Cadence^P** (steps/min)

Cadence = $\frac{\text{Steps (\#)}}{\text{Time (seconds)}} \times 60$

Marching on the spot instructions

"Once you are in the standing position, we will ask you to march on the spot. We would like you to march on the spot for as long as you can. We are going to record how long you walk for and how many steps you do. The test is designed to record your maximum exercise ability, so it is very important that you march on the spot for as long as you possibly can."

Give standardized encouragement every 10 seconds: "Keep going for as long as you can", "You're doing very well", "Well done". If applicable (ie retest), then: "Last time you performed the test, you marched for . . . and did . . . steps."

5. 30 SECOND SIT TO STAND → Assessor blinded? Yes No

Reason # not done (specify) _____

1. Sit to stand repetitions completed (#) Attempted + unable (if checked, insert score = "0" in "sit to stand repetitions completed")

2. Level of assistance required 0 people 1 person 2 people (or more)

3. Location Bed Chair → Armrest used? Yes No

6. 2 MINUTE WALK TEST → Assessor blinded? Yes No

Reason # not done (specify) _____

1. Distance OR Attempted + unable (if checked, insert score = "0" in "distance")

(1 metre = 3.28 feet) (metres) (feet)

2. Level of assistance required 0 people 1 person 2 people (or more)

3. Gait aid used [#; 1 = None, 2 = Cane or crutches, 3 = Walker, 4 = Other (specify)] (specify) _____

Comments _____

CYCLE RCT #142

Plate #044

Visit #040

Patient ID [] [] [] 1 [] [] [] (site #) (patient #) Coded Patient Initials [] [] F L Therapist(s) Initials [] [] [] [] F M L F M L Test Date [] [] [] [] [] [] 2 0 [] [] (dd/mm/yyyy)

STRENGTH AND FUNCTION ASSESSMENT: HOSPITAL DISCHARGE (SF4)

Reason # not done

- | | |
|---------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| 1. Assessment (ax) merged with other ax form/ other timepoint (complete q# 1B) | 8. Cognitive issue - patient unable to follow commands |
| 2. Patient did not pass cog. screen. prior to ICU discharge (alive @ discharge) | 9. Assessor perceives patient unable to perform due to safety concerns (e.g. physiological or physical) |
| 3. Patient died prior to reaching timepoint | 10. Assessor perceives that patient is likely able to but has a limitation such as pain, lines, amputation, fatigue etc. |
| 4. Goals of care changed to palliative | 11. Other assessment prioritized |
| 5. Patient or Proxy refusal | 12. Other (specify) |
| 6. Assessment missed | |
| 7. Cognitive issue - patient too sedated/agitated | |

1A. Any part of assessment completed/ any clinical data

Yes (go to 1B)
 No (insert reason # not done, if "other", specify) → [] []
 (specify) _____

1B. Clinical data should apply to the following timepoints (check all)

ICU Awakening	ICU Discharge	3 D Post-ICU Discharge	Hospital Discharge
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. STRENGTH (MMT) → Assessor blinded? Yes No

[] [] Reason # not done (specify) _____

MUSCLE	RIGHT		LEFT		MUSCLE	RIGHT		LEFT	
	SCORE	Reason # not done	SCORE	Reason # not done		SCORE	Reason # not done	SCORE	Reason # not done
1. Shoulder Flexion ^P	[] /5	[] []	[] /5	[] []	5. Hip Flexion	[] /5	[] []	[] /5	[] []
2. Shoulder Abduction	[] /5	[] []	[] /5	[] []	6. Knee Extension ^P	[] /5	[] []	[] /5	[] []
3. Elbow Flexion	[] /5	[] []	[] /5	[] []	7. Ankle Dorsiflexion	[] /5	[] []	[] /5	[] []
4. Wrist Extension	[] /5	[] []	[] /5	[] []					

3. SIT TO STAND: ASSISTANCE REQUIRED^P → Assessor blinded? Yes No

[] [] Reason # not done (specify) _____

1. **Level of assistance required^P** 0 people 1 person 2 people (or more) Attempted + unable
 2. Location Bed Chair → Armrest used? Yes No

4. MARCHING ON THE SPOT: CADENCE^P → Assessor blinded? Yes No

[] [] Reason # not done (specify) _____

1. Steps [] [] [] (#) Attempted + unable (if checked, insert score = "0" in "steps")

2. Time [] [] : [] [] = [] [] []
 (mm : sec) (seconds)

3. **Cadence^P** [] [] [] (steps/min)

$$Cadence = \frac{Steps \ (#)}{Time \ (seconds)} \times 60$$

Marching on the spot instructions
 "Once you are in the standing position, we will ask you to march on the spot. We would like you to march on the spot for as long as you can. We are going to record how long you walk for and how many steps you do. The test is designed to record your maximum exercise ability, so it is very important that you march on the spot for as long as you possibly can."
 Give standardized encouragement every 10 seconds: "Keep going for as long as you can", "You're doing very well", "Well done". If applicable (ie retest), then: "Last time you performed the test, you marched for . . . and did . . . steps."

5. 30 SECOND SIT TO STAND → Assessor blinded? Yes No

[] [] Reason # not done (specify) _____

1. Sit to stand repetitions completed [] [] (#) Attempted + unable (if checked, insert score = "0" in "sit to stand repetitions completed")
 2. Level of assistance required 0 people 1 person 2 people (or more)
 3. Location Bed Chair → Armrest used? Yes No

6. 2 MINUTE WALK TEST → Assessor blinded? Yes No

[] [] Reason # not done (specify) _____

1. Distance [] [] [] OR [] [] [] [] Attempted + unable (if checked, insert score = "0" in "distance")
 (1 metre = 3.28 feet) (metres) (feet)

2. Level of assistance required 0 people 1 person 2 people (or more)

3. Gait aid used [#; 1 = None, 2 = Cane or crutches, 3 = Walker, 4 = Other (specify)] (specify) _____

Comments _____



CYCLE RCT #142

Plate #051

Visit #090

Patient ID [] [] 1 [] [] (site #) (patient #)

Coded Patient Initials [] [] F L

Assessor Initials [] [] F L

Date of Assessment [] [] [] [] 2 0 [] [] (dd/mm/yyyy)

ICU AWAKENING: INTENSIVE CARE PSYCHOLOGICAL ASSESSMENT TOOL (IPAT) (Form RC 1)

© University College London Hospitals NHS Foundation Trust

Reason # not done

1. Was any clinical data collected at this timepoint?

[] Yes [] No (insert reason #, if "other", specify) -> [] [] (specify) _____

- 1. (Intentionally omitted) 2. Patient did not pass cog. screen. prior to ICU discharge (alive @ discharge) 3. Patient died prior to reaching timepoint 4. Goals of care changed to palliative 5. Patient or Proxy refusal 6. Assessment missed 7. Cognitive issue - patient too sedated/agitated 8. Cognitive issue - patient unable to follow commands 9. (Intentionally omitted) 10. (Intentionally omitted) 11. Other assessment prioritized 12. Other (specify)

"I would like to ask you some questions about your stay in intensive care, and how you've been feeling in yourself. These feelings can be an important part of your recovery. To answer, please circle the answer that is closest to how you feel, or answer in any way you are able to (e.g. by speaking or pointing)"

Table with 4 columns: Question, A, B, C. Rows 1-10 with Likert scale options (No, Yes, a bit, Yes, a lot).

Do you have any comments to add in relation to any of the answers?

TOTAL SCORE [] [] /20

Approximate time to complete assessment? [] [] (min)

Patient intubated during assessment? [] Yes [] No

Location of ax? [] ICU [] Other (specify) _____

SCORING

Any answer in column A = 0 points Any answer in column B = 1 point Any answer in column C = 2 points

Sum up the scores of each item for a total IPAT score out of 20 Cut-off point >= 7 indicates patient at risk

CYCLE RCT #142

Plate #052

Visit #090

Patient ID (site #) 1 (patient #)

Coded Patient Initials F L

Assessor Initials F L

Date of Assessment (dd/mm/yyyy) 20

RESEARCH COORDINATOR ASSESSMENT: ICU DISCHARGE (Form RC 2.1 of 2)

1. Was the patient alive at ICU discharge?

Yes/No (do not collect ADL data; go to 3A)

2. Activities of Daily Living (ADL) (Ask the patient the following AND/OR review chart regarding their current function; check ONE box per activity)

Table with columns: ACTIVITY, INDEPENDENT, DEPENDENT. Rows include BATHING, DRESSING, GOING to the TOILET, TRANSFER, CONTINENCE, FEEDING.

Reason # not done

- 1. Assessment (ax) merged with other ax form/ other timepoint (complete q# 3B)
2. (Intentionally omitted)
3. Patient died prior to reaching timepoint
4. Goals of care changed to palliative
5. Patient or Proxy refusal
6. Assessment missed
7. Cognitive issue - patient too sedated/agitated
8. Cognitive issue - patient unable to follow commands
9. (Intentionally omitted)
10. (Intentionally omitted)
11. Other assessment prioritized
12. Other (specify)

3A. Any part of assessment completed/ any clinical data

Yes/No (insert reason # not done, if "other", specify) ->

3B. Clinical data should apply to the following timepoints (check all)

ICU Discharge, Hospital Discharge checkboxes

4. Patient-Reported Functional Scale (Ask the patient the following questions; insert all activity scores into table below; do not score based on chart review)

Reason # not done (specify)

Instructions: "I'm going to ask you about how well you think you can do 6 activities. Compared to before you got sick, can you rate how well you can do each of these activities? Today, do you, or would you have difficulty with the following items? Please point to the number which best describes your ability. 10 = as well as you could before the ICU, and 0 = unable to do this activity right now." (If the patient reports the activity is not relevant to them, please state, "If you are not doing this now, do you imagine you would have any difficulty?")

Unable to perform activity 0 1 2 3 4 5 6 7 8 9 10 Able to perform activity at same level as before ICU admission

Table with columns: ACTIVITY, SCORE. Rows include 1. Rolling in bed, 2. Moving from lying in the bed to sitting at the edge of the bed, 3. Moving from sitting to standing, 4. Transferring from bed to chair, 5. Walking the length of a football field (100 m / 110 yards), 6. Climbing 1 flight of stairs (10 steps), SUM TOTAL, FINAL SCORE (sum total / 6)



CYCLE RCT #142

Plate #053

Visit #090

Patient ID (site #) 1 (patient #)

Coded Patient Initials F L

Assessor Initials F L

Date of Assessment (dd/mm/yyyy) 20

RESEARCH COORDINATOR ASSESSMENT: ICU DISCHARGE (Form RC 2.2 of 2)

Reason # not done

- 1. Assessment (ax) merged with other ax form/ other timepoint (complete q# 3B)
2. (Intentionally omitted)
3. Patient died prior to reaching timepoint
4. Goals of care changed to palliative
5. Patient or Proxy refusal
6. Assessment missed
7. Cognitive issue - patient too sedated/agitated
8. Cognitive issue - patient unable to follow commands
9. (Intentionally omitted)
10. (Intentionally omitted)
11. Other assessment prioritized
12. Other (specify)

5. EQ-5D: Descriptive System: Today's Perception

Reason # not done (specify)

Instructions: Read the 5 descriptions from each heading to the patient

Under each heading, tick ONE box that best describes your health TODAY

MOBILITY

- I have no problems in walking about
I have slight problems in walking about
I have moderate problems in walking about
I have severe problems in walking about
I am unable to walk about

SELF-CARE

- I have no problems washing or dressing myself
I have slight problems washing or dressing myself
I have moderate problems washing or dressing myself
I have severe problems washing or dressing myself
I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
I have slight problems doing my usual activities
I have moderate problems doing my usual activities
I have severe problems doing my usual activities
I am unable to do my usual activities

PAIN / DISCOMFORT

- I have no pain or discomfort
I have slight pain or discomfort
I have moderate pain or discomfort
I have severe pain or discomfort
I have extreme pain or discomfort

ANXIETY / DEPRESSION

- I am not anxious or depressed
I am slightly anxious or depressed
I am moderately anxious or depressed
I am severely anxious or depressed
I am extremely anxious or depressed

6. EQ-5D: Visual Analogue Scale: Today's Perception

Reason # not done (specify)

Instructions: Read to the following to the patient:

We would like to know how good or bad your health is TODAY.

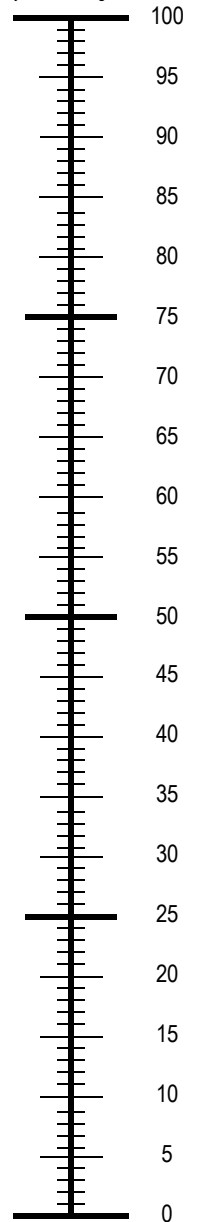
This scale is numbered from 0 - 100.

100 means the best health you can imagine
0 means the worst health you can imagine

Mark an X on the scale to indicate how your health is TODAY.

Now, please write the number you marked on the scale in the box below.

The best health you can imagine



The worst health you can imagine

YOUR HEALTH SCORE TODAY

Score input box

CYCLE RCT #142

Plate #054

Visit #090

Patient ID [] [] 1 [] [] (site #) (patient #)

Coded Patient Initials [] [] F L

Assessor Initials [] [] F L

Date of Assessment [] [] [] [] 2 0 [] [] (dd/mm/yyyy)

RESEARCH COORDINATOR ASSESSMENT: HOSPITAL DISCHARGE (Form RC 3.1 of 4)

1. Was the patient alive at hospital discharge?

- Yes
No (do not collect ADL and Frailty data; go to 4A)

2. Activities of Daily Living (ADL) (Ask the patient the following AND/OR review chart regarding their current function; check ONE box per activity)

Table with 3 columns: ACTIVITY, INDEPENDENT, DEPENDENT. Rows include BATHING, DRESSING, GOING to the TOILET, TRANSFER, CONTINENCE, FEEDING.

3. Hospital Discharge Admission Frailty Scale (Considering the patient's status at hospital discharge, please select the highest score from the descriptions below from 1 to 9. If the patient has characteristics from higher descriptors, then please report the highest score)

FRAILTY SCORE [] (1-9)



1. VERY FIT: People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.



2. WELL: People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, e.g. seasonally



3. MANAGING WELL: People whose medical problems are well controlled, but are not regularly active beyond routine walking.



4. VULNERABLE: While not dependent on others for daily help, often symptoms limit activities. A common complaint is being "slowed up", and/or being tired during the day.



5. MILDLY FRAIL: These people often have more evident slowing, and need help in high order IADLS (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.



6. MODERATELY FRAIL: People who need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.



7. SEVERELY FRAIL: Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).



8. VERY SEVERELY FRAIL: Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.



9. TERMINALLY ILL: Approaching the end of life. This category applies to people with a life expectancy <6 months, who are not otherwise evidently frail.

Scoring frailty in people with dementia: The degree of frailty corresponds to the degree of dementia.

Common symptoms in mild dementia include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In moderate dementia, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In severe dementia, they cannot do personal care without help.



CYCLE RCT #142

Plate #055

Visit #090

Patient ID [] [] 1 [] [] (site #) (patient #)

Coded Patient Initials [] [] F L

Assessor Initials [] [] F L

Date of Assessment [] [] [] [] 2 0 [] [] (dd/mm/yyyy)

RESEARCH COORDINATOR ASSESSMENT: HOSPITAL DISCHARGE (Form RC 3.2 of 4)

Reason # not done

- 1. Assessment (ax) merged with other ax form/ other timepoint (complete q# 4B)
2. (Intentionally omitted)
3. Patient died prior to reaching timepoint
4. Goals of care changed to palliative
5. Patient or Proxy refusal
6. Assessment missed
7. Cognitive issue - patient too sedated/agitated
8. Cognitive issue - patient unable to follow commands
9. (Intentionally omitted)
10. (Intentionally omitted)
11. Other assessment prioritized
12. Other (specify)

4A. Any part of assessment completed/ any clinical data

Yes (go to 4B)
No (insert reason # not done, if "other", specify) -> [] [] (specify)

4B. Clinical data should apply to the following timepoints (check all)

ICU Discharge []
Hospital Discharge []

5. Patient-Reported Functional Scale (Ask the patient the following questions; insert all activity scores into table below; do not score based on chart review)

[] [] Reason # not done (specify)

Instructions: "I'm going to ask you about how well you think you can do 6 activities. Compared to before you got sick, can you rate how well you can do each of these activities? Today, do you, or would you have difficulty with the following items? Please point to the number which best describes your ability. 10 = as well as you could before the ICU, and 0 = unable to do this activity right now." (If the patient reports the activity is not relevant to them, please state, "If you are not doing this now, do you imagine you would have any difficulty?")

Unable to perform activity 0 1 2 3 4 5 6 7 8 9 10 Able to perform activity at same level as before ICU admission

Table with 2 columns: ACTIVITY and SCORE. Rows include: 1. Rolling in bed, 2. Moving from lying in the bed to sitting at the edge of the bed, 3. Moving from sitting to standing, 4. Transferring from bed to chair, 5. Walking the length of a football field (100 m / 110 yards), 6. Climbing 1 flight of stairs (10 steps), SUM TOTAL, FINAL SCORE (sum total / 6)



CYCLE RCT #142

Plate #056

Visit #090

Patient ID (site #) 1 (patient #)

Coded Patient Initials F L

Assessor Initials F L

Date of Assessment (dd/mm/yyyy) 20

RESEARCH COORDINATOR ASSESSMENT: HOSPITAL DISCHARGE (Form RC 3.3 of 4)

Reason # not done

- 1. Assessment (ax) merged with other ax form/ other timepoint (complete q# 4B)
2. (Intentionally omitted)
3. Patient died prior to reaching timepoint
4. Goals of care changed to palliative
5. Patient or Proxy refusal
6. Assessment missed
7. Cognitive issue - patient too sedated/agitated
8. Cognitive issue - patient unable to follow commands
9. (Intentionally omitted)
10. (Intentionally omitted)
11. Other assessment prioritized
12. Other (specify)

6. EQ-5D: Descriptive System: Today's Perception

Reason # not done (specify)

Instructions: Read the 5 descriptions from each heading to the patient

Under each heading, tick ONE box that best describes your health TODAY

MOBILITY

- I have no problems in walking about
I have slight problems in walking about
I have moderate problems in walking about
I have severe problems in walking about
I am unable to walk about

SELF-CARE

- I have no problems washing or dressing myself
I have slight problems washing or dressing myself
I have moderate problems washing or dressing myself
I have severe problems washing or dressing myself
I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
I have slight problems doing my usual activities
I have moderate problems doing my usual activities
I have severe problems doing my usual activities
I am unable to do my usual activities

PAIN / DISCOMFORT

- I have no pain or discomfort
I have slight pain or discomfort
I have moderate pain or discomfort
I have severe pain or discomfort
I have extreme pain or discomfort

ANXIETY / DEPRESSION

- I am not anxious or depressed
I am slightly anxious or depressed
I am moderately anxious or depressed
I am severely anxious or depressed
I am extremely anxious or depressed

7. EQ-5D: Visual Analogue Scale: Today's Perception

Reason # not done (specify)

Instructions: Read to the following to the patient:

We would like to know how good or bad your health is TODAY.

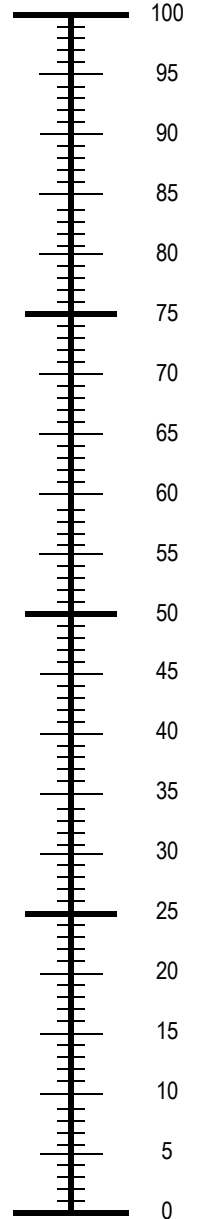
This scale is numbered from 0 - 100.

100 means the best health you can imagine
0 means the worst health you can imagine

Mark an X on the scale to indicate how your health is TODAY.

Now, please write the number you marked on the scale in the box below.

The best health you can imagine



The worst health you can imagine

YOUR HEALTH SCORE TODAY

Score input box



CYCLE RCT #142

Plate #057

Visit #090

Patient ID [] [] 1 [] [] (site #) (patient #)

Coded Patient Initials [] [] F L

Assessor Initials [] [] F L

Date of Assessment [] [] [] [] 2 0 [] [] (dd/mm/yyyy)

RESEARCH COORDINATOR ASSESSMENT: HOSPITAL DISCHARGE (Form RC 3.4 of 4)

Reason # not done

- 1. Assessment (ax) merged with other ax form/ other timepoint (complete q# 4B) 7. Cognitive issue - patient too sedated/agitated
2. (Intentionally omitted) 8. Cognitive issue - patient unable to follow commands
3. Patient died prior to reaching timepoint 9. (Intentionally omitted)
4. Goals of care changed to palliative 10. (Intentionally omitted)
5. Patient or Proxy refusal 11. Other assessment prioritized
6. Assessment missed 12. Other (specify)

8. EQ-5D: Descriptive System: Pre-hospital perception

[] [] Reason # not done (specify)

Instructions: Read the 5 descriptions from each domain to the patient and ask them to select ONE descriptor.

Imagine a normal day before you were admitted to the hospital... Thinking about this day how would you rate your health? Under each heading, please tick ONE box that best describes your health on a normal day.

MOBILITY

- I have no problems in walking about
I have slight problems in walking about
I have moderate problems in walking about
I have severe problems in walking about
I am unable to walk about

SELF-CARE

- I have no problems washing or dressing myself
I have slight problems washing or dressing myself
I have moderate problems washing or dressing myself
I have severe problems washing or dressing myself
I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
I have slight problems doing my usual activities
I have moderate problems doing my usual activities
I have severe problems doing my usual activities
I am unable to do my usual activities

PAIN / DISCOMFORT

- I have no pain or discomfort
I have slight pain or discomfort
I have moderate pain or discomfort
I have severe pain or discomfort
I have extreme pain or discomfort

ANXIETY / DEPRESSION

- I am not anxious or depressed
I am slightly anxious or depressed
I am moderately anxious or depressed
I am severely anxious or depressed
I am extremely anxious or depressed

9. EQ-5D: Visual Analogue Scale: Pre-hospital perception

[] [] Reason # not done (specify)

Instructions: Read to the following to the patient:

Imagine a normal day before you were admitted to the hospital. We would like to know how good or bad your health is on a normal day.

This scale is numbered from 0 - 100.

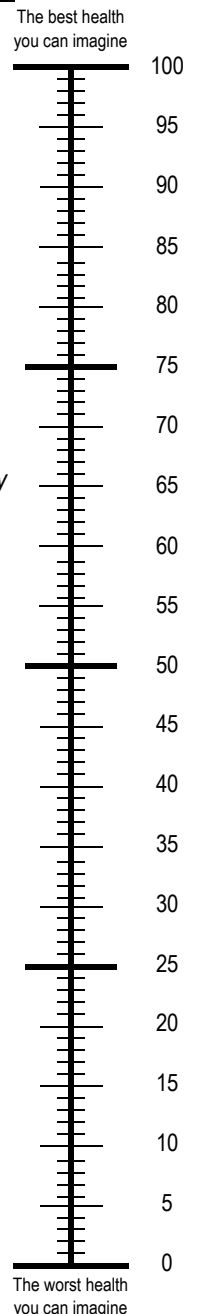
100 means the best health you can imagine
0 means the worst health you can imagine

Thinking about this day, mark an X on the scale to indicate how you would rate your health on a normal day

Now, please write the number you marked on the scale in the box below.

YOUR HEALTH SCORE ON A NORMAL DAY

[] [] []





CYCLE RCT #142

Plate #060

(Week #) 1

Patient ID (site #) 1 (patient #)

Coded Patient Initials F L

PT/ REHABILITATION POST-LAST STUDY DAY (Form 6)

Record patient's PT treatment received once Daily Data Form 4 collection has stopped (patient reached last study day) until hospital d/c OR until patient has been discharged from PT/rehabilitation services OR once 26 weeks of form 6 data collection completed.

Date First Column (dd/mm/yyyy) 20

Date Last Column (dd/mm/yyyy) 20

Last Form 6? No Yes

Table with 8 columns and 5 rows for data entry. Rows include Day of week, Date (d/m/y), Patient discharged from PT/rehab service, Patient refused PT/rehab, and PT/rehab not received.

Rehab Therapy Treatment Received [check ALL activities performed during the treatment session (with or without assistance)]

Table with 8 columns and 13 rows for rehab therapy treatment received. Rows include Passive, Activity in bed, Passive to chair, Sit @ E.O.B., Standing, Tx bed to chair, M.O.S. 2 steps/ft, Walk Ax2, Walk Ax1, Walk indep w/ aid, Walk indep no aid, Stairs, and Chest PT.

Comments

Definitions: Physiotherapy / Rehabilitation Treatment Received

- 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 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
12) Chest PT / Airway Clearance



CYCLE RCT #142

Plate #070

Visit #090

Patient ID [] [] [1] [] [] (site #) (patient #)

Coded Patient Initials [] [] F L

Assessor Initials [] [] F L

90 DAY FOLLOW-UP QUESTIONNAIRE (Form RC 4.1 of 13)

Assessment Collection Window:

83 - 120 days post-randomization (ideal = day 90)

SDM/ LAR Can Provide Data For:

Section A = ALL Parts

Section B = ONLY Part 1 "Frailty" (Parts 2, 3, 4 = completed via patient interview or SDM/LAR with patient input)

- 1. Date of randomization [] [] [2] [0] [] [] (dd/mm/yyyy)
2. Date of 90 days post-randomization [] [] [2] [0] [] [] (dd/mm/yyyy)
3. Date range of assessment [] [] [2] [0] [] [] (start date) -> [] [] [2] [0] [] [] (end date)
(If start date = end date, enter same date in both fields)

4. At time of follow-up/ date of assessment, was the patient alive?

[] Unknown (only choose this if directed by the methods centre; stop here)

[] No -> Record date of death: [] [] [2] [0] [] [] (dd/mm/yyyy)

-> Before they died, did the patient spend any time in the following locations:

Home/Retirement Home, Assisted Living Facility, Nursing Home, Long Term Care Facility, Chronic Care Facility

[] No -> (Stop here)

[] Yes -> (Complete Section A only; go to page 4.2)

[] Yes -> At the time of follow-up, did the patient spend any time in the following locations since hospital discharge:

Home/Retirement Home, Assisted Living Facility, Nursing Home, Long Term Care Facility, Chronic Care Facility

[] No -> (Complete Section B only; go to page 4.2)

[] Yes -> (Complete Sections A + B; go to page 4.2)

*Section A does not need to be completed if the patient has only spent time in any the following locations since randomization: hospital, inpatient rehabilitation, long term acute care, skilled nursing facility

**If the patient has spent time in locations not listed above, and you are unsure if section A should be completed, please contact the methods centre for guidance prior to starting the assessment.



CYCLE RCT #142

Plate #071

Visit #090

Patient ID 1 Coded Patient Initials

(site #) (patient #) F L

90 DAY FOLLOW-UP QUESTIONNAIRE (Form RC 4.2 of 13)

Introduction

“Hello (*insert name of patient/SDM/LAR*), my name is (*insert name of research personnel*). I am calling from (*insert name of institution*) regarding the CYCLE research study that you participated in during your stay in the Intensive Care Unit in (*insert ICU admission month*). This study is investigating the use of in-bed cycling for patients requiring a breathing machine in the ICU. I am calling you today to follow-up to see how you are doing 3 months after you began in the study. I was hoping I could speak with you for a few minutes to ask you some questions about your health and function. This should take no longer than ___ minutes. Would that be okay?”

If **yes**, continue with the follow-up questionnaire.

If **no**, ask them if there is a better time to complete the interview. Re-inforce the importance of the follow-up interview (i.e. helps us to determine if the treatment you received was beneficial in the long-term, provides you with information regarding your recovery, helps us learn the best way to care for future patients in the ICU like yourself) and the timelines associated with the follow-up call. If the patient still does not want to complete the interview, thank them for their time and end the call.

Record who is completing the assessment (i.e. patient or SDM/ LAR) and whether or not consent was obtained. If assessment is not being completed, record the reason not done code on the following page.

6. Assessment being completed by (check ALL):
 (If being completed by SDM/LAR with patient input, check both boxes) Patient SDM/ LAR

7. Patient/SDM/LAR consents to assessment: Yes No (specify)

If you are leaving a voicemail, ensure not to disclose PHI or breach PHIPA rules: “Hello this message is for (*insert name of patient*). My name is (*insert name of research personnel*) and I am calling from (*insert name of institution*) regarding the CYCLE research study that you have been involved in since your stay in hospital. I am calling to follow-up with you to see how you are doing since leaving the hospital and to ask you some questions. Please give me a call back at your earliest convenience. You can reach me at (*insert phone number here*). Thank you.”

If you are told that a study participant has died, express your condolences as below: “I am very sorry to hear that (*insert name of patient*) has passed away. This must be a difficult time for you.” Allow the contact to express themselves. When appropriate, ask the contact if you can continue to ask them some questions regarding the study. Complete section A of questionnaire only. Closing the call: “Thank you very much for taking the time to talk with me. I am very sorry to hear about your loss. Take care.”

If you are calling an alternate contact person: “(*insert patient name*) provided your name as a person who we could call to try to reach him/her. I hope that you can help us to contact him/her.”

If patient states they have never heard of study and don’t know why they were enrolled: Politely explain the study and why they were enrolled. Ask them for consent to continue with the assessment: “While you were in the ICU and on a breathing machine, your family member or friend enrolled you in the CYCLE study. The CYCLE study investigates whether patients who receive routine physiotherapy and in-bed cycling while on a breathing machine in the ICU do better than those who receive routine physiotherapy only. We want to learn about how you have been doing since your discharge from the hospital. We will be asking you some questions about your health care needs, quality of life, and physical function. Your answers to these questions will be kept confidential. Do you have any questions? Is it okay if I continue with the questionnaire?”



CYCLE RCT #142

Plate #072

Visit #090

Patient ID [] [] [] [] 1 [] [] [] [] (site #) (patient #)

Coded Patient Initials [] [] F L

Date of Assessment [] [] [] [] 20 [] [] (dd/mm/yyyy)

90 DAY FOLLOW-UP QUESTIONNAIRE (Form RC 4.3 of 13)

SECTION A: UTILIZATION

Please complete this section if patient spent time in any of the following locations since date of randomization: Home/ Retirement Home, Assisted Living Facility, Nursing Home, Long Term Care Facility, Chronic Care Facility

- Reason # not done
1 = Unable to contact patient or SDM/LAR
2 = Patient/ SDM/ LAR does not provide consent (patient/ SDM /LAR contacted)
3 = Patient/ SDM/ LAR refusal (consent acquired)
4 = Assessor perceives patient unable to perform and SDM/ LAR not available
5 = Other (specify)

Reason # not done (if "other", specify)

"Firstly, I would like to ask you some questions about your health care needs and ability to return to your daily activities since being discharged from hospital. If you have information recorded on the patient log provided to you at hospital discharge it would be helpful for you to have this on hand as we go through the questions."

Part 1: Patient Disposition and Living Facilities

1.1 Where are you currently living (if patient not alive at time of follow-up, where were they living previously)?

- Unknown Home (independent) Assisted Living Facility (mostly independent) Inpatient Rehabilitation
Home (w/ home care) Nursing Home/ Long Term Care Facility Acute Care Hospital
Home (w/unpaid caregiver assistance) Chronic Care Facility/ Complex Continuing Care/ Skilled Nursing Facility Other (specify)
Retirement Home (independent) Long Term Acute Care (LTAC)

1.2 Marital status (check ONE box)

- Unknown Single Married or Common law Separated or Divorced Other (specify)

1.3 Since your hospital discharge, have you had any admissions to a long term care facility?

- Unknown No Yes -> How many days? (# days) Unknown

1.4 Since your hospital discharge, have you spent any time in a retirement home?

- Unknown No Yes -> How many days? (# days) Unknown

1.5 Since your hospital discharge, have you spent any time in an assisted living facility?

- Unknown No Yes -> How many days? (# days) Unknown

1.6 Since your hospital discharge, have you spent any time in/ in a chronic care facility/ complex continuing care/ skilled nursing facility?

- Unknown No Yes -> How many days? (# days) Unknown

1.7 Since your hospital discharge, have you spent any time in long term acute care (LTAC)?

- Unknown No Yes -> How many days? (# days) Unknown

1.8 Since your hospital discharge, have you spent any time in an inpatient rehab?

- Unknown No Yes -> How many days? (# days) Unknown

1.9 Since your hospital discharge, have you spent any time in any other locations not listed above (e.g. drug rehab facility)?

- Unknown No Yes (specify)

Part 2: Emergency Room Visits and Hospitalizations

2.1 Since your hospital discharge, have you visited an emergency room for any reason?

- Unknown No Yes -> How many times? (# visits) Unknown

[Interviewer: For each emergency room visit, ask the patient the reason for the visit]

VISIT #1: Unknown Reason:

VISIT #2: Unknown Reason:

VISIT #3: Unknown Reason:



CYCLE RCT #142

Plate #073

Visit #090

Patient ID [] [] [1] [] [] (site #) (patient #)

Coded Patient Initials [] [] F L

Date of Assessment [] [] [2] [0] [] [] (dd/mm/yyyy)

90 DAY FOLLOW-UP QUESTIONNAIRE (Form RC 4.4 of 13)

2.2 Since your hospital discharge, have you been admitted to a hospital overnight, for any reason?

Unknown
 No Yes → How many times? [] [] (# admissions) Unknown

[Interviewer: For each hospitalization, ask the patient the reason for the hospitalization, any major surgeries/procedures performed, where they were discharged to, admission and discharge dates (or estimated length of stay if not known), and number of days in ICU/CCU during their admission]

ADMISSION #1

a) Reason: Unknown Yes (specify) → _____
b) Major Surgery/ Procedure: Unknown No Yes (specify) → _____
c) Admit Date: Unknown [] [] [2] [0] [] [] (dd/mm/yyyy)
d) Admit to ICU/CCU: Unknown No Yes (specify) → [] [] (# of Days) Unknown
e) Discharged? No (enter ANTICIPATED d/c date) → [] [] [2] [0] [] [] (dd/mm/yyyy) Unknown
 Unknown Yes → (enter ACTUAL d/c date) [] [] [2] [0] [] [] (dd/mm/yyyy) Unknown
→ (enter d/c location): _____ Unknown

ADMISSION #2

a) Reason: Unknown Yes (specify) → _____
b) Major Surgery/ Procedure: Unknown No Yes (specify) → _____
c) Admit Date: Unknown [] [] [2] [0] [] [] (dd/mm/yyyy)
d) Admit to ICU/CCU: Unknown No Yes (specify) → [] [] (# of Days) Unknown
e) Discharged? No (enter ANTICIPATED d/c date) → [] [] [2] [0] [] [] (dd/mm/yyyy) Unknown
 Unknown Yes → (enter ACTUAL d/c date) [] [] [2] [0] [] [] (dd/mm/yyyy) Unknown
→ (enter d/c location): _____ Unknown

ADMISSION #3

a) Reason: Unknown Yes (specify) → _____
b) Major Surgery/ Procedure: Unknown No Yes (specify) → _____
c) Admit Date: Unknown [] [] [2] [0] [] [] (dd/mm/yyyy)
d) Admit to ICU/CCU: Unknown No Yes (specify) → [] [] (# of Days) Unknown
e) Discharged? No (enter ANTICIPATED d/c date) → [] [] [2] [0] [] [] (dd/mm/yyyy) Unknown
 Unknown Yes → (enter ACTUAL d/c date) [] [] [2] [0] [] [] (dd/mm/yyyy) Unknown
→ (enter d/c location): _____ Unknown



CYCLE RCT #142

Plate #074

Visit #090

Patient ID [] [] [1] [] [] (site #) (patient #)

Coded Patient Initials [] [] F L

Date of Assessment [] [] [] [] [2] [0] [] [] (dd/mm/yyyy)

90 DAY FOLLOW-UP QUESTIONNAIRE (Form RC 4.5 of 13)

Part 3: Family Doctor Visits

3.1 Since your hospital discharge, have you been to see your family doctor for any reason?

- Unknown (go to 4.1)
No (go to 4.1)
Yes -> How many visits? (# visits)
Unknown

3.2 Do you feel any of these family doctor visits were because of your initial admission to the ICU 3 months ago

- Unknown
No
Yes -> How many visits? (# visits)
Unknown

Part 4: Specialist Visits

4.1 Since your hospital discharge, have you visited a specialist for any reason?

- Unknown (go to 5.1)
No (go to 5.1)
Yes (complete table below)

[Interviewer: If yes, ask the patient about the type(s) of specialist(s), the number of visits to each, and how many of these visits were because of their admission to ICU]

Table with columns: Specialist, Visited/ Seen (Unknown, No, Yes), Visits (Unknown, #), Visits related to initial ICU admission (Unknown, #), Reimbursed by government and/ or insurance plan (Unknown, No, Yes). Rows include Neurologist, Respiriologist/ Pulmonologist, Cardiologist, Dermatologist, Ear/Nose/Throat Specialist, Gastroenterologist, Psychiatrist (Rehabilitation Doctor), Nephrologist, Psychiatrist, Surgeon, Dentist, and two 'Other' rows.



CYCLE RCT #142

Plate #075

Visit #090

Patient ID 1
 (site #) (patient #)

Coded Patient Initials
 F L

Date of Assessment 2 0
 (dd/mm/yyyy)

90 DAY FOLLOW-UP QUESTIONNAIRE (Form RC 4.6 of 13)

Part 5: Other Healthcare Professionals/ Services

5.1 Since your hospital discharge, have you seen any other healthcare professionals or used any of the following services for any reason?

- Unknown (go to 6.1A)
 No (go to 6.1A) Yes (complete table below)

[Interviewer: If yes, ask the patient about the type(s) of professional(s), the number of visits to each, and how many of these visits were because of their admission to ICU]

Professional	Visited/ Seen			Visits		Visits related to initial ICU admission		Reimbursed by government and/ or insurance plan		
	Unknown.	No	Yes	Unknown.	(#)	Unknown.	(#)	Unknown.	No	Yes
Nurse Practitioner	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Visiting Nurse (e.g. Home Care)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Private Nurse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Homemaker/ Personal Support Worker	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Physiotherapist/ Physical Therapist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Occupational Therapist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Speech Language Pathologist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Respiratory Therapist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dietitian	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Social Worker	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Psychologist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Chiropractor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Naturopath/ Homeopath	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Employment Retraining Services	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Meals-on-wheels	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Transportation Services (e.g. DARTS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



CYCLE RCT #142

Plate #077

Visit #090

Patient ID 1
(site #) (patient #)

Coded Patient Initials
F L

Date of Assessment 2 0
(dd/mm/yyyy)

90 DAY FOLLOW-UP QUESTIONNAIRE (Form RC 4.7 of 13)

Part 6: Assistance from Others (e.g. spouse, relative, friend, other caregiver)

6.1 Since your hospital discharge, have you required assistance from others to help you with your daily activities?

- Unknown
- No → (go to 7.1)
- Yes

6.2 For how many weeks did you require assistance from others with your daily activities?

- Unknown
- (# weeks)

6.3 For how many hours on average in a typical week did you require this assistance?

- Unknown
- (# hours)

6.4 Was the person who was assisting you working?

- Unknown
- No → (go to 7.1)
- Yes

6.5 Did this person have to take time off work?

- Unknown
- No → (go to 7.1)
- Yes

6.6 How many days did this person have to take off from work?

- Unknown
- (# days)



CYCLE RCT #142

Plate #076

Visit #090

Patient ID [] [] [1] [] [] (site #) (patient #)

Coded Patient Initials [] [] F L

Date of Assessment [] [] [] [] [2] [0] [] [] (dd/mm/yyyy)

90 DAY FOLLOW-UP QUESTIONNAIRE (Form RC 4.8 of 13)

Part 7: Employment Status and Time-off-work from Paid Employment

7.1A How many hours per week are you currently working?

Unknown [] [] (# hours)

7.1B Before you were admitted to the ICU 3 months ago, which of the following best describes your employment status or main activity?

[Interviewer: Read list and tick one box only]

- Unknown
- (1) Working at a full-time job (>35 hours/week)
- (2) Working at a part-time job (<35 hours/week)
- ▶ **If (1) or (2) go to Q7.2**
- (3) Employed but on temporary sick leave or long-term disability
- (4) Looking for work/between jobs
- (5) Going to school
- (6) Homemaking
- (7) Retired
- (8) Other (specify) _____

—▶ **If (3) to (8) Section A is complete (do not complete 7.2 to 7.4)**

7.2 If you were working full-time/part-time before your admission to the ICU, how many hours/week were you working in a typical week?

Unknown [] [] (# hours)

7.3 Have you returned to work since your ICU admission 3 months ago?

- Unknown
- No —▶ (Section A is complete)
- Yes —▶ (go to 7.4)

7.4 What was the date of your first day back at work; number of weeks after hospital discharge patient returned to work?

Unknown [] [] [] [] [2] [0] [] [] (dd/mm/yyyy)

OR

[] [] (# weeks)

END SECTION A

****Stop here if the patient died during hospital stay relative to the index admission****

Continue to Section B if patient is alive at the time of follow-up



CYCLE RCT #142

Plate #078

Visit #090

Patient ID [] [] [1] [] []
(site #) (patient #)

Coded Patient Initials [] []
F L

Date of Assessment [] [] [] [] [2] [0] [] []
(dd/mm/yyyy)

90 DAY FOLLOW-UP QUESTIONNAIRE (Form RC 4.9 of 13)

SECTION B: PATIENT REPORTED OUTCOMES

Please complete this section if patient is alive at the time of follow-up

**Section must be completed by patient or by SDM/LAR with patient input, with the exception that "Clinical Frailty Scale" can be completed by SDM/LAR only.*

Reason # not done

- | | |
|---------------------------------------------------|--------------------------------------------------------|
| 1. (Intentionally omitted) | 8. Cognitive issue - patient unable to follow commands |
| 2. (Intentionally omitted) | 9. (Intentionally omitted) |
| 3. (Intentionally omitted) | 10. (Intentionally omitted) |
| 4. (Intentionally omitted) | 11. Other assessment prioritized |
| 5. Patient or Proxy refusal | 12. Other (specify) |
| 6. Assessment missed | |
| 7. Cognitive issue - patient too sedated/agitated | |

Part 1: Clinical Frailty Scale

[Interviewer: Ask the patient questions as necessary to discern their level of frailty based on the scale below. The following are some questions that may help clarify the patient's health status, level of activity, and functional status]

2.1 Do you need help with the following activities?

- | | | |
|----------------------------------------------------------|-----------------------------------------------------------|-------------------------------------------|
| <input type="checkbox"/> Bathing (if so, how much help?) | <input type="checkbox"/> Dressing (if so, how much help?) | <input type="checkbox"/> Transportation |
| <input type="checkbox"/> Light housekeeping | <input type="checkbox"/> Heavy housework | <input type="checkbox"/> Finances |
| <input type="checkbox"/> Outside activities | <input type="checkbox"/> Taking medications | <input type="checkbox"/> Meal preparation |

2.2 Do you experience any disease symptoms throughout your day (e.g. SOB, pain, headache, etc.)?

- No Yes → do these symptoms limit your activities or cause you to feel slowed up and/or tired throughout the day?
- No Yes

2.3 How are you managing with the stairs? _____

2.4 How often do you exercise?

- Regularly Seasonally or occasionally Not regularly beyond routine walking

2.4 Do you feel fitter than most people your age?

- No Yes

[Interviewer: please select the highest score from the descriptions below from 1 to 9. If the patient has characteristics from higher descriptors, then please report the highest score.]



CYCLE RCT #142

Plate #079

Visit #090

Patient ID (site #) 1 (patient #)

Coded Patient Initials F L

Date of Assessment 20

90 DAY FOLLOW-UP QUESTIONNAIRE (Form RC 4.10 of 13)

*Section can be completed by SDM/LAR only, patient or SDM/LAR with patient input.

Considering the patient's current status, please select the highest score from the descriptions below from 1 to 9. If the patient has characteristics from higher descriptors, then please report the highest score.

Reason # not done (specify)



1. VERY FIT: People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.



2. WELL: People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally, e.g. seasonally



3. MANAGING WELL: People whose medical problems are well controlled, but are not regularly active beyond routine walking.

SCORE

Score input box



4. VULNERABLE: While not dependent on others for daily help, often symptoms limit activities. A common complaint is being "slowed up", and/or being tired during the day.



5. MILDLY FRAIL: These people often have more evident slowing, and need help in high order IADLS (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.



6. MODERATELY FRAIL: People who need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.



7. SEVERELY FRAIL: Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).



8. VERY SEVERELY FRAIL: Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness



9. TERMINALLY ILL: Approaching the end of life. This category applies to people with a life expectancy <6 months, who are not otherwise evidently frail.

Scoring frailty in people with dementia: The degree of frailty corresponds to the degree of dementia.

Common symptoms in mild dementia include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In moderate dementia, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In severe dementia, they cannot do personal care without help.

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As of March 31, 2023 (Live Version 3); Replaces November 30, 2021 (Live Version 2)



CYCLE RCT #142

Plate #080

Visit #090

Patient ID (site #) 1 (patient #)

Coded Patient Initials F L

Date of Assessment (dd/mm/yyyy) 20

90 DAY FOLLOW-UP QUESTIONNAIRE (Form RC 4.11 of 13)

*Section must only be completed by patient or SDM/LAR with patient input.

Part 2: EQ-5D

1. "I will read several statements pertaining to a particular topic to you and I would like you to tell me which best describe your health today." "The next section of this questionnaire focuses on quality of life."

[Interviewer: Read each statement for each category and tick the corresponding box to the patient's response]

2. "We would like to know how good or bad your health is today. Picture a scale numbered from 0 to 100. 100 means the best health you can imagine. 0 means the worst health you can imagine. Where on this scale would you place your health today?"

[Interviewer: Record the number between 0-100 in the provided box]

1. EQ-5D: Descriptive System: Today's Perception

Reason # not done (specify)

2. EQ-5D: Visual Analogue Scale: Today's Perception

Reason # not done (specify)

MOBILITY

- I have no problems in walking about
I have slight problems in walking about
I have moderate problems in walking about
I have severe problems in walking about
I am unable to walk about

SELF-CARE

- I have no problems washing or dressing myself
I have slight problems washing or dressing myself
I have moderate problems washing or dressing myself
I have severe problems washing or dressing myself
I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
I have slight problems doing my usual activities
I have moderate problems doing my usual activities
I have severe problems doing my usual activities
I am unable to do my usual activities

PAIN / DISCOMFORT

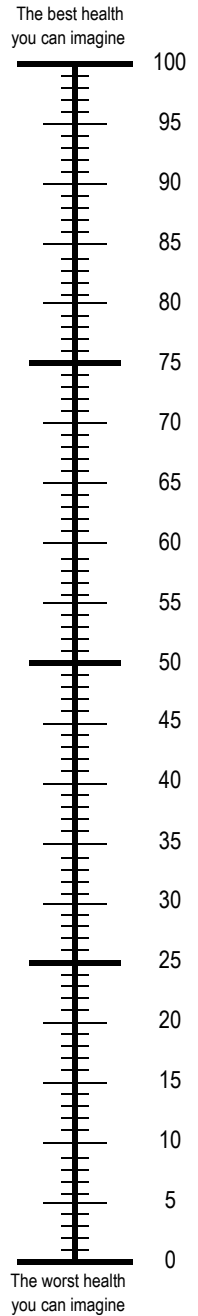
- I have no pain or discomfort
I have slight pain or discomfort
I have moderate pain or discomfort
I have severe pain or discomfort
I have extreme pain or discomfort

ANXIETY / DEPRESSION

- I am not anxious or depressed
I am slightly anxious or depressed
I am moderately anxious or depressed
I am severely anxious or depressed
I am extremely anxious or depressed

YOUR HEALTH SCORE TODAY

Health score input box





CYCLE RCT #142

Plate #081

Visit #090

Patient ID [] [] 1 [] [] (site #) (patient #)

Coded Patient Initials [] [] F L

Date of Assessment [] [] [] [] 2 0 [] [] (dd/mm/yyyy)

90 DAY FOLLOW-UP QUESTIONNAIRE (Form RC 4.12 of 13)

*Section must only be completed by patient or SDM/LAR with patient input.

Part 3: Hospital Anxiety and Depression Scale

[] Reason # not done (specify)

"I will now read some statements and replies to you that relate to anxiety and depression. For each statement, please let me know which reply is the closest to how you have been feeling in the past week."

[Interviewer: Tick the box beside the patient's response for each question. See the scoring instructions below. The patient will receive a separate score for each Depression and Anxiety]

Hospital Anxiety (A) and Depression (D) Scale (HADS)

Table with 14 rows of statements and 12 columns for D and A scores (0, 1, 2, 3). Includes statements like 'I feel tense or wound up', 'I still enjoy things I used to enjoy', etc.

SCORING

SUM

Scoring table with rows for DEPRESSION TOTAL and ANXIETY TOTAL, and columns for calculations: [] x 0 = [] [], [] x 1 = [] [], [] x 2 = [] [], [] x 3 = [] [], and a final SUM column.

Scoring Instructions: Add up the number of checkmarks in each vertical column and write the total on the blank line at the bottom of that column. Multiply each column's total by the corresponding score for that column (0, 1, 2, or 3) and write this in the blank box. Add up the total of the boxes horizontally across each row to determine the separate total scores for both depression and anxiety

(0-7 = Normal ; 8-10 = Borderline Abnormal ; 11-21 = Abnormal)



CYCLE RCT #142

Plate #082

Visit #090

Patient ID 1
(site #) (patient #)

Coded Patient Initials
F L

Date of Assessment 2 0
(dd/mm/yyyy)

90 DAY FOLLOW-UP QUESTIONNAIRE (Form RC 4.13 of 13)

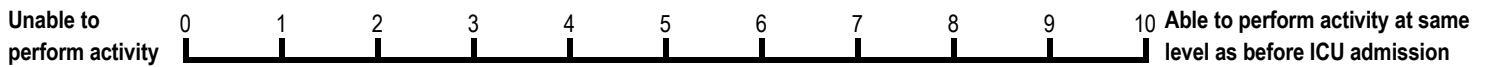
**Section must only be completed by patient or SDM/LAR with patient input.*

Part 4: Patient-Reported Functional Scale - ICU

Reason # not done (specify) _____

"I'm going to ask you about how well you think you can do 6 activities **today**, compared to your ability to do them before your ICU admission. Picture a scale from 0 to 10. 10 means you can do the activity as well as you could before your ICU admission. 0 means you are unable to do this activity now."

[Interviewer: Read the activities from 1-6 and record patient's score in the provided box. If the patient reports the activity is not relevant to them, please state, "If you are not doing this now, do you imagine you would have any difficulty?"]



ACTIVITY	SCORE
1. Rolling in bed	<input type="text"/> <input type="text"/> /10
2. Moving from lying in the bed to sitting at the edge of the bed	<input type="text"/> <input type="text"/> /10
3. Moving from sitting to standing	<input type="text"/> <input type="text"/> /10
4. Transferring from bed to chair	<input type="text"/> <input type="text"/> /10
5. Walking the length of a football field (100 m / 110 yards)	<input type="text"/> <input type="text"/> /10
6. Climbing 1 flight of stairs (10 steps)	<input type="text"/> <input type="text"/> /10
SUM TOTAL	<input type="text"/> <input type="text"/> /60
FINAL SCORE (sum total / 6)	<input type="text"/> <input type="text"/> <input type="text"/>

END SECTION B

CYCLE RCT #142

Plate #099

Visit #100

Patient ID [] [] [] 1 [] [] [] (site #) (patient #)

Coded Patient Initials [] [] F L

FINAL STATUS (Form 7.1 of 2)

1. Was the patient discharged from ICU alive?

[] Yes (enter date of discharge) [] No (enter date of death; go to Q3) [] [] [] [] 2 0 [] [] (dd/mm/yyyy)

2. If alive, where was the patient discharged?

- [] CCU / Stepdown / Surgical Stepdown
[] Ward
[] Other ICU (specify)
[] Home (independent)
[] Home (with home care)
[] Home (with unpaid caregiver assistance)
[] Retirement Home (independent)
[] Assisted Living Facility (mostly independent)
[] Nursing Home/Long Term Care Facility
[] Chronic Care Facility/Complex Continuing Care Skilled Nursing Facility
[] Long Term Acute Care (LTAC)
[] Inpatient Rehabilitation
[] Other Hospital (specify)
[] Other (specify)

3. What was the highest level of patient function on the day of ICU discharge?

[] Bedbound [] Sitting at edge of bed [] Standing [] Walking [] Data not available (reason)

4. Did the patient still require invasive mechanical ventilation at ICU discharge?

[] No [] Yes

5. Measured weight at ICU discharge

[] Not available [] [] [] (#) [] kg [] lbs

6. Was an ICU discharge order written (or "consult medicine for transfer")?

[] No [] Yes (enter date) [] [] [] [] 2 0 [] [] (dd/mm/yyyy)

7. Was the patient readmitted to the ICU?

[] No [] Yes (specify # readmissions) [] (#)

8. Was the patient discharged from the hospital alive?

[] Yes (enter date of discharge) [] No (enter date of death; go to Q10) [] [] [] [] 2 0 [] [] (dd/mm/yyyy)

9. If alive, where was the patient discharged?

- [] Home (independent)
[] Home (with home care)
[] Home (with unpaid caregiver assistance)
[] Retirement Home (independent)
[] Assisted Living Facility (mostly independent)
[] Nursing Home/Long Term Care Facility
[] Chronic Care Facility/Complex Continuing Care Skilled Nursing Facility
[] Long Term Acute Care (LTAC)
[] Inpatient Rehabilitation
[] Other Hospital (specify)
[] Other (specify)

10. What was the highest level of patient function on the day of hospital discharge?

[] Bedbound [] Sitting at edge of bed [] Standing [] Walking [] Data not available (reason)

11. Measured weight at hospital discharge

[] Not available [] [] [] (#) [] kg [] lbs

12. Was the patient declared ALC (alternate level of care)/attente de transfer or acute care services no longer required?

[] Yes (enter date) [] No [] [] [] [] 2 0 [] [] (dd/mm/yyyy)

13. Was the patient alive at 90 days post-randomization?

[] Unknown [] Yes (enter date of 90 days post-randomization) [] No (enter date of death) [] [] [] [] 2 0 [] [] (dd/mm/yyyy)



CYCLE RCT #142

Plate #100

Visit #100

Patient ID **1**
(site #) (patient #)

Coded Patient Initials
F L

FINAL STATUS (Form 7.2 of 2)

14. Was this patient co-enrolled in another study?

No Yes (complete table)

	RCT	Design		Funding			Methods Centre Internal Study Code
		Observational		Academic	Industry	Local	
1. _____	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
<u>Study Name</u> 2. _____	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
3. _____	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>
4. _____	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/>

15. Strength and Function assessment form completion status

<u>Column A</u>	<u>Column B</u>	<u>Column C</u>			
Strength & Function Assessment Forms	Any part of ax completed/ any clinical data recorded “Yes” = complete “ <u>Column C</u> ” “No” = only “reason # not done” section(s) on Ax form complete (i.e. no clinical data recorded)	Clinical data should apply to the following timepoints (check all)			
		ICU Awakening	ICU Discharge	3 D Post-ICU Discharge	Hospital Discharge
ICU Awakening (SF1)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ICU Discharge (SF2)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3 Days Post-ICU Discharge (SF3)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hospital Discharge (SF4)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

16. Research Coordinator assessment form completion status

<u>Column A</u>	<u>Column B</u>	<u>Column C</u>			
Research Coordinator Assessment Forms	Any part of ax completed/ any clinical data recorded “Yes” = complete “ <u>Column C</u> ” (if applicable) “No” = only “reason # not done” section(s) on Ax form complete (i.e. no clinical data recorded)	Clinical data should apply to the following timepoints (check all)			
		ICU Awakening	ICU Discharge	3 D Post-ICU Discharge	Hospital Discharge
IPAT (RC1)	<input type="checkbox"/> Yes <input type="checkbox"/> No				
RC ICU Discharge (RC2)	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/>		<input type="checkbox"/>
RC Hospital Discharge (RC3)	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/>		<input type="checkbox"/>
90 Day Follow-up Questionnaire (RC4)	<input type="checkbox"/> Yes <input type="checkbox"/> No				