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Cambridge University Hospitals NHS Foundation Trust

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PRotocolised Evaluation of permiSSive blood pressure targets versus Usual caRE (PRESSURE)

Chief Investigator: Dr David Inwald

Refresher Training

Agenda

- Aim
- Trial Design
- Eligibility
- Screening & Enrolment
- Randomisation
- Consent
- Safety Reporting
- Governance
- Next steps
- CRF refresher

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Aim

To evaluate the clinical and cost-effectiveness of a permissive blood pressure target (MAP target of 5th centile for age), to guide treatment (as compared with usual care) in critically ill children with hypotension.

Research Question

- **P**opulation — Mechanically ventilated critically ill children receiving vasoactive drugs for hypotension
- **I**ntervention — Permissive blood pressure target (MAP target 5th centile for age) in order to minimise dose and duration of medical interventions
- **C**omparator — Usual care
- **O**utcome — Composite outcome of mortality and duration of ventilator support at 30 days

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Trial Design

- Pragmatic, multi-centre, parallel group randomised clinical trial
- 1900 patients
- 17 paediatric critical and intensive care units (PICUs) and associated PICU retrieval services
- 30-month recruitment period (November 2021- May 2024)
- Each participant will be followed up with a questionnaire at 12 months post randomisation to assess HrQoL
- Internal pilot - traffic light progression criteria in first six months of recruitment period

Intervention

Permissive Blood Pressure Target

- Those patients randomised to permissive blood pressure will be allocated their target range based on age (5th centile MAP threshold to 5th centile MAP threshold + 5 mmHg)

Age range (completed months/years)	Target range
less than 6 months	40 - 43
6 months – less than 1 year	40 - 45
1 - 3 years	45 - 50
4 - 9 years	50 - 55
≥10 years	55 - 60

- MAP should be within range whilst receiving vasoactive drugs

- Decision to discontinue vasoactive drugs depends on ability to maintain MAP above the 5th centile threshold
- Permissive blood pressure range will apply if the patient requires vasoactive drugs whilst on PICU, including readmission from another inpatient area
- Vasoactives should only be restarted if MAP is lower than the 5th centile threshold
- Post extubation, if vasoactives are restarted 5th centile threshold should apply
- If patient develops exclusion criterion after randomisation, treating clinician's discretion as to whether the permissive blood pressure target range is continued

Usual Care

- Patients in the control arm will receive usual care (as per local practices)

- Usual care will apply at any point the patient requires vasoactive drugs whilst on PICU during the acute hospital admission, including readmissions to PICU from another inpatient care area

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Eligibility

Inclusion Criteria

- Age >37 weeks corrected gestational age and <16 years
- Accepted for or admitted to PICU
- Receiving a continuous infusion of vasoactive drug for hypotension commenced within previous 6 hours
- Vasoactive drug expected to continue for at least 6 hours or more
- On invasive mechanical ventilation

Exclusion Criteria

- Admitted post cardiac surgery
- Known cardiomyopathy
- Neonates with suspected or proven duct dependent circulation
- Brain injury
- Pulmonary hypertension
- Malignant hypertension
- Death perceived as imminent
- Previously recruited to PRESSURE

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Screening and Enrolment

- Screening and Enrolment Log - Excel spreadsheet
- Record all patients who are:
  - Accepted for or admitted to PICU & receiving vasoactive drugs
- Which will include
  - eligible patients randomised
  - eligible patients not randomised
  - patients meeting one or more exclusion criteria

See SOP 003 – Patient screening and enrolment

Screening and Enrolment Log

- Each row on the spreadsheet represents a patient
- Section A: Child details

	Section A: Child details			
Hospital Number/ Local Identifier (remove prior to submission to ICNARC)	Start of vasoactive drugs (dd/mm/yy)	Start of vasoactive drugs (hh:mm)	Date of screening (dd/mm/yy)	Time of screening (hh:mm)

Screening and Enrolment Log

- Section B: Inclusion criteria

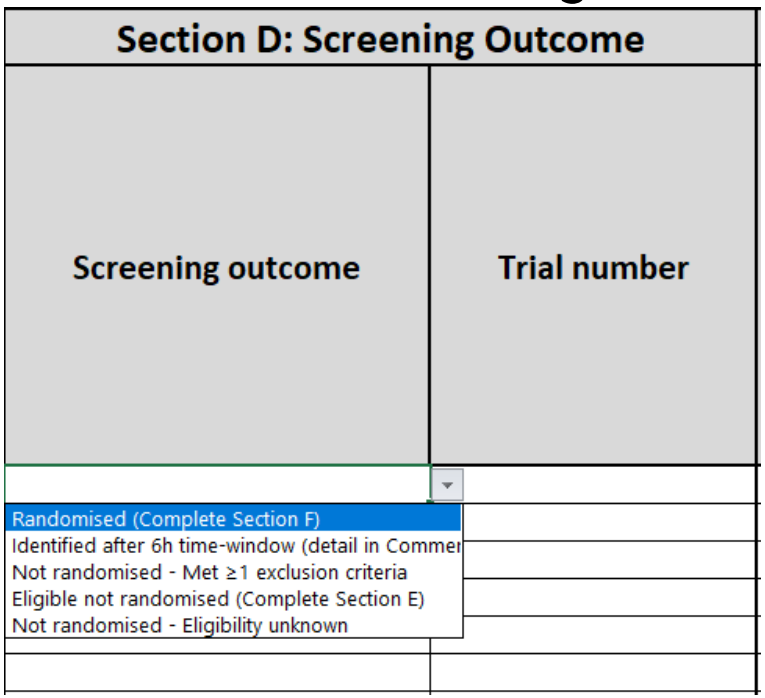
Section B: Inclusion criteria				
Age >37 weeks corrected gestational age to ≤16 years	Accepted for or admitted to PICU	Receiving a continuous infusion of vasoactive drug for hypotension commenced within previous 6 hours	Vasoactive drug expected to continue for at least 6 hours or more	On invasive mechanical ventilation
Yes / No				

- Section C: Exclusion criteria

Section C: Exclusion criteria (mark 'x' in relevant column if exclusion criteria met)							
Admitted post cardiac surgery	Known cardiomyopathy	Neonates with suspected or proven duct dependent circulation	Brain injury	Pulmonary hypertension	Malignant hypertension	Death perceived as imminent	Previously recruited to PRESSURE

Screening and Enrolment Log

- Section D: Screening outcome



- Spreadsheet set up to indicate which fields should/should not be completed based on selection

Screening and Enrolment Log

- Section E and Section F (complete as appropriate)

	Section E	Section F	
er	**If eligible but not randomised, *(select reason and explain in Comments section)***	**Is patient enrolled in other studies? If yes, please list which studies**	**Comments**

- Missed, e.g. patient was not picked up by staff
- Clinician declines enrolment
- Co-enrolment issue
- Other
- Previously enrolled into PRESSURE

Screening and Enrolment Log

- Submit regularly to ICNARC CTU
- e.g. fortnightly
- email to pressure@icnarc.org
- Retrieval teams do not need to maintain log but should provide details to receiving hospital when child is brought in so can be recorded.

Do not include any identifiable information when submitting the Log

Co-enrolment in other studies

Consider co-enrolment with PRESSURE on a study-by-study basis

- Oxy-PICU – no (If participating in Oxy-PICU please consider all patients that are not on vasoactive drugs for randomisation to Oxy-PICU)
- PICNIC - yes
- PROSpect – under review
- Observational studies – yes if logged with CTU

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Randomisation

Web randomisation

- Email pressure@icnarc.org to request account
- https://www.sealedenvelope.com/access

Telephone randomisation

- Study number for PRESSURE 2996
- 3-digit investigator number for each site (is also start of trial ID)

- Trained staff on training log, GCP not required

- Retrieval teams will get own Randomisation Form

See SOP 004 – Patient Randomisation

www.icnarc.org

Randomisation Form

Patient Initials / Hospital Number:

Eligibility check

Inclusion – all must be yes

Age >37 weeks corrected gestational and <16 years	Yes (Y) No (N)
Accepted for or admitted to PICU	Yes (Y) No (N)
Receiving a continuous infusion of vasoactive drug for hypotension commenced within previous 6 hours*	Yes (Y) No (N)
Vasoactive drug expected to continue for 6 hours or more	Yes (Y) No (N)
On invasive mechanical ventilation	Yes (Y) No (N)

Please Note: If the patient is not on vasoactive drugs please consider them for Oxy-PICU

Exclusion – all must be no

Admitted post cardiac surgery	Yes (Y) No (N)
Known cardiomyopathy	Yes (Y) No (N)
Neonates with suspected or proven duct dependent circulation	Yes (Y) No (N)
Brain injury	Yes (Y) No (N)
Pulmonary hypertension	Yes (Y) No (N)
Malignant hypertension	Yes (Y) No (N)
Death perceived as imminent	Yes (Y) No (N)
Previously recruited to PRESSURE	Yes (Y) No (N)

If all inclusion criteria are "Yes" and all exclusion criteria are "No" dial:
020 3384 6368
Study number: 2996 **Investigator number:** xxx
or log on to: https://www.sealedenvelope.com/access

How to randomise

Telephone/web randomisation

Does the patient meet all inclusion criteria? Yes (1) No (2)

Does the patient meet any exclusion criteria? Yes (1) No (2)

Age: (In completed years or months) Y Y — if less than 1yr put '0' in years (YY), then complete months (MM) M M

When did patient commence continuous infusion of vasoactive drug for hypotension? Today (1) Yesterday (2) H H : M M (24-hour clock)

What is the patient's Mean Arterial Pressure at randomisation? ___ mmHg

Details required by randomisation service

Details from randomisation service

Randomisation: Permissive Blood Pressure Target (P) Usual care (C)

Confirmation of randomisation

If randomised to "Permissive Blood Pressure Target", please tick off the correct limit on the right hand table

	Age range (completed months/years)	Target Range
☐	Less than 6 months	40 - 43
☐	6 months - less than 1 year	40 - 45
☐	1 - 3 years	45 - 50
☐	4 - 9 years	50 - 55
☐	≥10 years	55 - 60

Date/time of randomisation: D D / M M / 2 0 2 Y — H H : M M (24-hour clock) Trial ID:

Randomised by: (print name)

Signature:

Eligibility confirmed by (if different to above): (print name)

Once complete, ensure form is stored in ISF

Sign off by trained staff member

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Consent

- Deferred consent
- The clinical/research nurse team will approach the parents/legal guardians as soon as practically possible and appropriate to discuss trial & provide participant documentation:

  - Parent / Legal Guardian Information Sheet
    (associated bereaved versions)
  - Parent / Legal Guardian Consent Form
    (associated bereaved versions)
  - Age appropriate Information Sheets
  - Assent Forms

- Check timing is appropriate & invite/encourage questions

PRotocolised Evaluation of permiSSive blood pressure targets versus Usual care
Consent Form - Parent or Legal Guardian,
Version 1.0, 10 February 2021

To be completed by the Researcher:	
Hospital name:	
Trial ID:	
Child's full name:	

To be completed by the Parent or Legal Guardian:

Once you have read and understood each statement – **if you agree, please write your initials in each box**

1.	I confirm that I have read and understood the Participant Information Sheet (version 1.0, 10 Feb 2021) for the above research study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2.	I understand that participation is voluntary, and that I am free to withdraw consent at any time, without giving any reason and without my child's medical care or legal rights being affected.	☐
3.	I agree for my child to continue to take part in this study.	☐
4.	I agree for the Hospital NHS Trust research team to access my child's medical records and collect and send the full anonymised dataset securely to the Intensive Care National Audit and Research Centre (ICNARC) which is coordinating the study.	☐
5.	I agree that identifiable data related to my child (including name, date of birth, postcode and NHS number), may be processed by individuals from ICNARC, NHS Digital or NHS Wales Informatics Service where it is relevant to the participation in this research.	☐
6.	I agree that my child's medical records, held by the NHS, may be looked at by authorised individuals from ICNARC, the Sponsor or regulatory authorities to check that the study is being carried out correctly.	☐
7.	I agree for ICNARC to send me a questionnaire to find out how my child is doing in one year's time.	☐
8.	I agree that the information collected in the study will be used to support other research in the future, and may be shared anonymously with other researchers.	☐
9.	I would like to be contacted about any future related studies.	☐

Discharge prior to consent

- At least one phone call
- Personalised cover letter, PIS, Consent Form posted
- If no response after four weeks, a follow up letter, PIS, Consent Form posted
- If nothing received within four weeks participant included

Bereaved Consent

- Site research team should work with colleagues/bereavement counsellors to establish whether the approach to obtain consent is appropriate before they leave hospital

- If deferred consent is not sought prior to departure, covering letter, bereaved-PIS and bereaved Consent Form to be posted (four weeks after randomisation)

- If no response after four weeks, a follow up letter, bereaved-PIS, bereaved- Consent Form posted

- If no response in four weeks participant included.

PRotocolised Evaluation of permiSSive blood pressure targets versus Usual care
Consent Form - Parent or Legal Guardian
Version 1.0, 10 February 2021

To be completed by the Researcher:	
Hospital name:	
Trial ID:	
Child's full name:	

To be completed by the Parent or Legal Guardian:

Once you have read and understood each statement – **if you agree, please write your initials in each box**

1.	I confirm that I have read and understood the Participant Information Sheet (Version 1, 10 Feb 2021) for the above research study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2.	I understand that participation is voluntary, and that I am free to withdraw consent at any time, without giving any reason and without my legal rights being affected.	☐
3.	I agree for the Hospital NHS Trust research team to access my child's medical records and collect and send the full anonymised dataset securely to the Intensive Care National Audit and Research Centre (ICNARC) which is coordinating the study.	☐
4.	I agree that my child's medical records, held by the NHS, may be looked at by authorised individuals from ICNARC, the Sponsor, or regulatory authorities to check that the study is being carried out correctly.	☐
5.	I agree that the information collected in the study will be used to support other research in the future, and may be shared anonymously with other researchers.	☐
6.	I agree for my contact details to be sent to ICNARC for any future related studies.	☐

Your signature:		Date:	

Non-consent / Withdrawal

- If parent/guardian withdraws consent at any time or refuses to give consent ('non-consent') their decision must be respected.
- All data up to the point of withdrawal will be retained and a minimised anonymised dataset will be collected and retained for monitoring safety and important trial outcomes (unless explicit requests otherwise).
- Use Withdrawal Form to record which aspects they are withdrawing from.
- To monitor non-consent, details should be added to MACRO.

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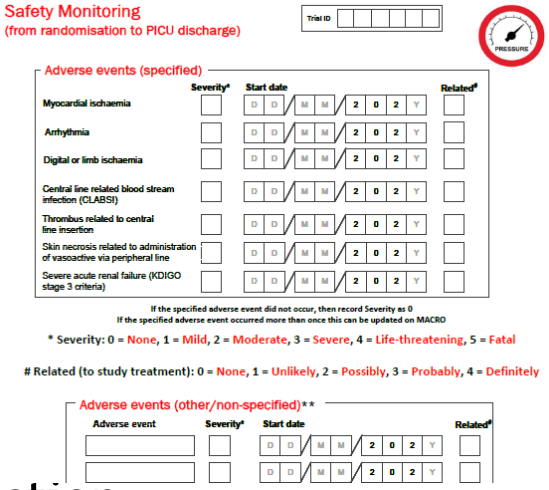
Safety Monitoring

- From randomisation until PICU discharge


Safety Monitoring
(from randomisation to PICU discharge)

Trial ID

Adverse events (specified)

	Severity*	Start date	Related#
Myocardial ischaemia		D D / M M / 2 0 2 Y	
Arrhythmia		D D / M M / 2 0 2 Y	
Digital or limb ischaemia		D D / M M / 2 0 2 Y	
Central line related blood stream infection (CLABSI)		D D / M M / 2 0 2 Y	
Thrombus related to central line insertion		D D / M M / 2 0 2 Y	
Skin necrosis related to administration of vasoactive via peripheral line		D D / M M / 2 0 2 Y	
Severe acute renal failure (KDIGO stage 3 criteria)		D D / M M / 2 0 2 Y	

If the specified adverse event did not occur, then record Severity as 0
If the specified adverse event occurred more than once this can be updated on MACRO

* Severity: 0 = None, 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life-threatening, 5 = Fatal

Related (to study treatment): 0 = None, 1 = Unlikely, 2 = Possibly, 3 = Probably, 4 = Definitely

Adverse events (other/non-specified)**

Adverse event	Severity*	Start date	Related#
		D D / M M / 2 0 2 Y	
		D D / M M / 2 0 2 Y	

- Adverse Events (AEs)

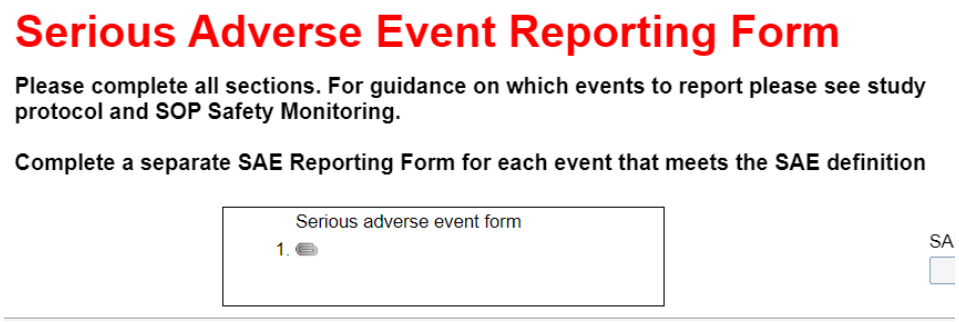
  Specified (expected)
  - myocardial ischaemia
  - arrhythmia
  - digital or limb ischaemia
  - central line related blood stream infection
  - thrombus related to central line insertion
  - Skin necrosis related to administration of vasoactives via peripheral line
  - Severe acute renal failure (KDIGO stage 3 criteria)

Other (unspecified / unexpected) - only reported if considered to be possibly, probably or definitely related to the study treatment (blood pressure or vasoactive drug administration)

Safety Monitoring

- Serious Adverse Events (SAEs)

- If severity of AE is severe, life-threatening or fatal
- Report on SAE Reporting Form
- Upload to MACRO
- ICNARC CTU must be informed within 24 hours of the site team becoming aware of the event



Serious Adverse Event Reporting Form

Please complete all sections. For guidance on which events to report please see study protocol and SOP Safety Monitoring.

Complete a separate SAE Reporting Form for each event that meets the SAE definition

Serious adverse event form

1.

SA

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Governance - Local

- Local confirmation of capacity and capability
  - Local site document packs sent
  - ISF available on PRESSURE ICNARC page
- Site responsibilities/activation
  - Signed Clinical Trial Site Agreement
  - Local C&C
  - Delegation Log and Staff Contacts Form
  - GCP certificate / CVs
  - Acknowledgment statements
  - Local R&D approval of SA1
  - Confirmation of screening/recruitment start date
- All needed prior to site activation

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Next steps

- Sites able to commence recruitment from November 2021
- Ensure confirmation of capacity and capability in place
- Ensure Substantial Amendment 1 R&D approval in place
- Return relevant sites responsibility / activation documents
- Inform us of commence screening / recruitment date

ICNARC CTU PRESSURE Team

Email: pressure@icnarc.org

Tel: 020 4514 6248 (Alanna Brown)
020 7831 6878(Raul Szekely)

https://www.icnarc.org/Our-Research/Studies/Current-Studies/Pressure

Any questions?

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Case Report Forms

- Randomisation Form
- Baseline – Demographics / Observations
  - Comorbidites
  - Functional status prior to PICU admission
- Observations
- Daily Values
- Organ support daily observations
- Outcomes - Functional status at PICU discharge
  - At hospital discharge
  - Survival status
- Consent/Assent
- Safety Monitoring
- Withdrawal
- SAE Reporting Form

See SOP 007 – Guidance for completion of Case Report Forms for further details

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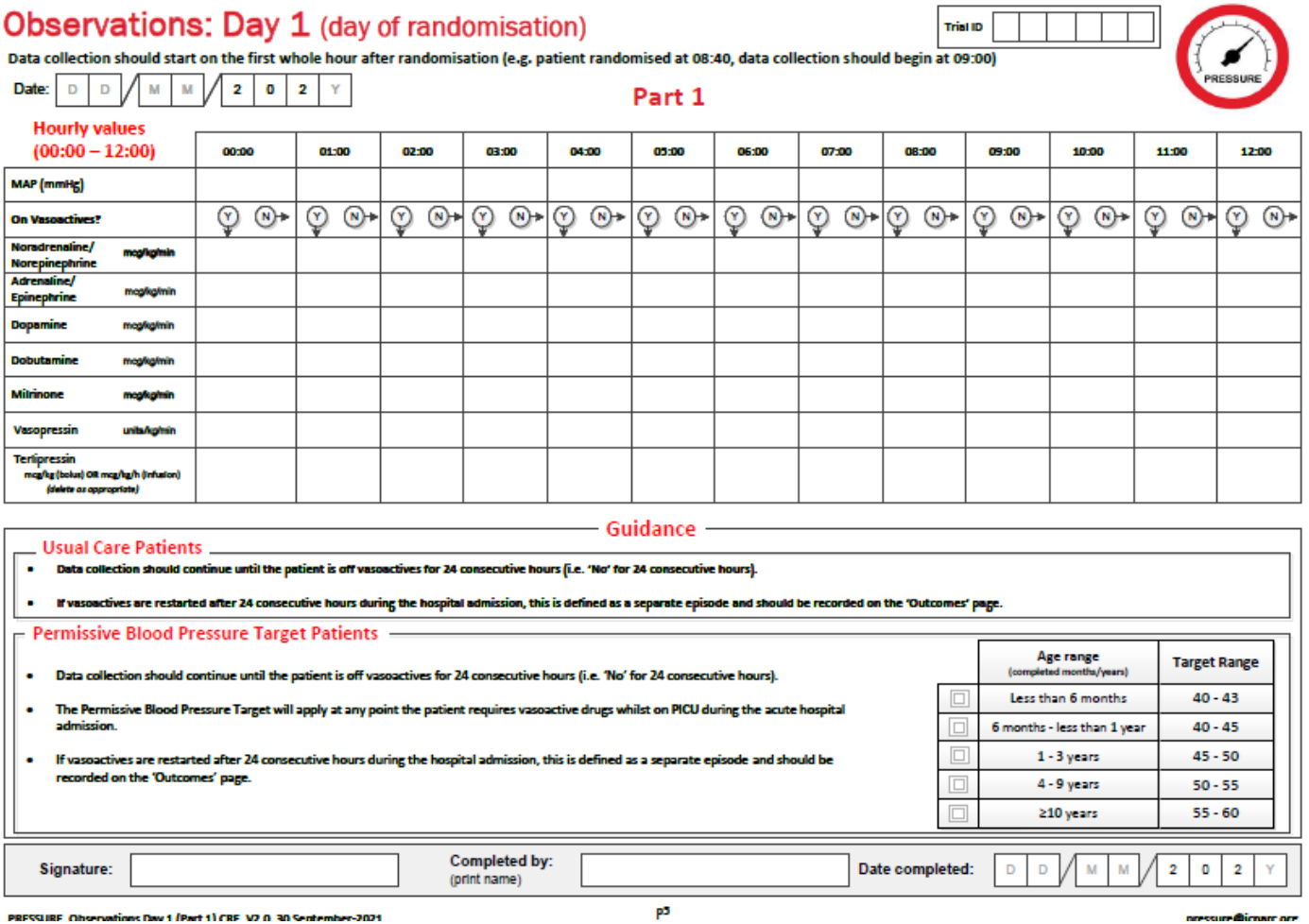


Observations: Day 1 (day of randomisation)

Trial ID

Data collection should start on the first whole hour after randomisation (e.g. patient randomised at 08:40, data collection should begin at 09:00)

Date: D D / M M / 2 0 2 Y

Part 1

Hourly values (00:00 – 12:00)	00:00	01:00	02:00	03:00	04:00	05:00	06:00	07:00	08:00	09:00	10:00	11:00	12:00
MAP (mmHg)													
On Vasoactives?	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N	Y N
Noradrenaline/ Norepinephrine mcg/kg/min													
Adrenaline/ Epinephrine mcg/kg/min													
Dopamine mcg/kg/min													
Dobutamine mcg/kg/min													
Milrinone mcg/kg/min													
Vasopressin units/kg/min													
Terlipressin mcg/kg (bolus) OR mcg/kg/h (infusion) (delete as appropriate)													

Guidance

Usual Care Patients

- Data collection should continue until the patient is off vasoactives for 24 consecutive hours (i.e. 'No' for 24 consecutive hours).
- If vasoactives are restarted after 24 consecutive hours during the hospital admission, this is defined as a separate episode and should be recorded on the 'Outcomes' page.

Permissive Blood Pressure Target Patients

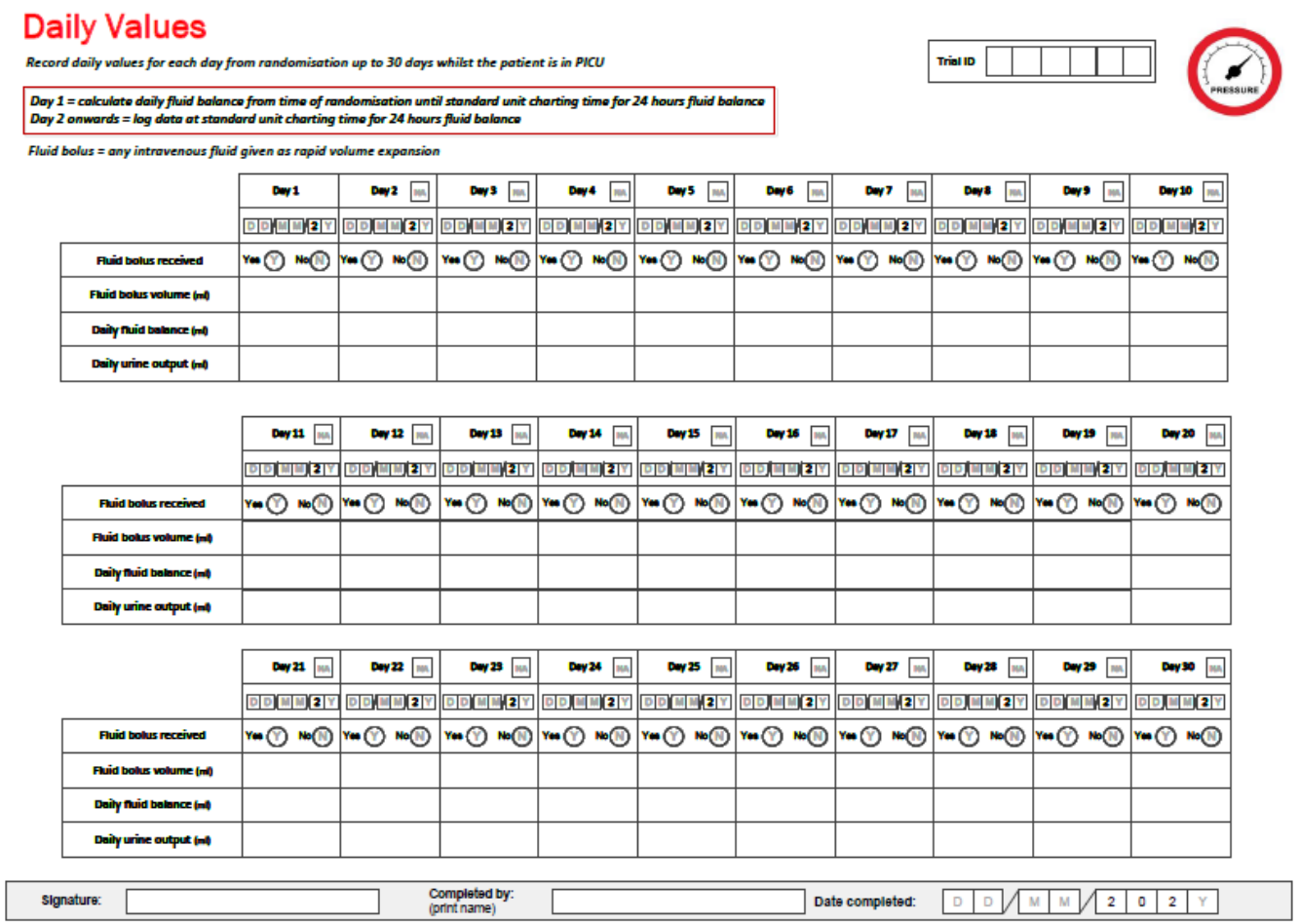
- Data collection should continue until the patient is off vasoactives for 24 consecutive hours (i.e. 'No' for 24 consecutive hours).
- The Permissive Blood Pressure Target will apply at any point the patient requires vasoactive drugs whilst on PICU during the acute hospital admission.
- If vasoactives are restarted after 24 consecutive hours during the hospital admission, this is defined as a separate episode and should be recorded on the 'Outcomes' page.

	Age range (completed months/years)	Target Range
☐	Less than 6 months	40 - 43
☐	6 months - less than 1 year	40 - 45
☐	1 - 3 years	45 - 50
☐	4 - 9 years	50 - 55
☐	≥10 years	55 - 60

Signature: | Completed by: (print name) | Date completed: D D / M M / 2 0 2 Y

PRESSURE Observations Day 1 (Part 1) CRF V2.0 30 September 2021 p3 pressure@icnarc.org

Deviation - MAP out of range for more than 3 consecutive observations



Daily Values

Record daily values for each day from randomisation up to 30 days whilst the patient is in PICU

Trial ID

Day 1 = calculate daily fluid balance from time of randomisation until standard unit charting time for 24 hours fluid balance
Day 2 onwards = log data at standard unit charting time for 24 hours fluid balance

Fluid bolus = any intravenous fluid given as rapid volume expansion

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10
	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y
Fluid bolus received	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N
Fluid bolus volume (ml)										
Daily fluid balance (ml)										
Daily urine output (ml)										

	Day 11	Day 12	Day 13	Day 14	Day 15	Day 16	Day 17	Day 18	Day 19	Day 20
	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y
Fluid bolus received	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N
Fluid bolus volume (ml)										
Daily fluid balance (ml)										
Daily urine output (ml)										

	Day 21	Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28	Day 29	Day 30
	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y	D D M M 2 Y
Fluid bolus received	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N	Yes Y No N
Fluid bolus volume (ml)										
Daily fluid balance (ml)										
Daily urine output (ml)										

Signature: | Completed by: (print name) | Date completed: D D / M M / 2 0 2 Y

Values recorded each day from randomisation up to 30 days whilst patient is in PICU.
(select N/A if pt discharged which will blank out any remaining days)

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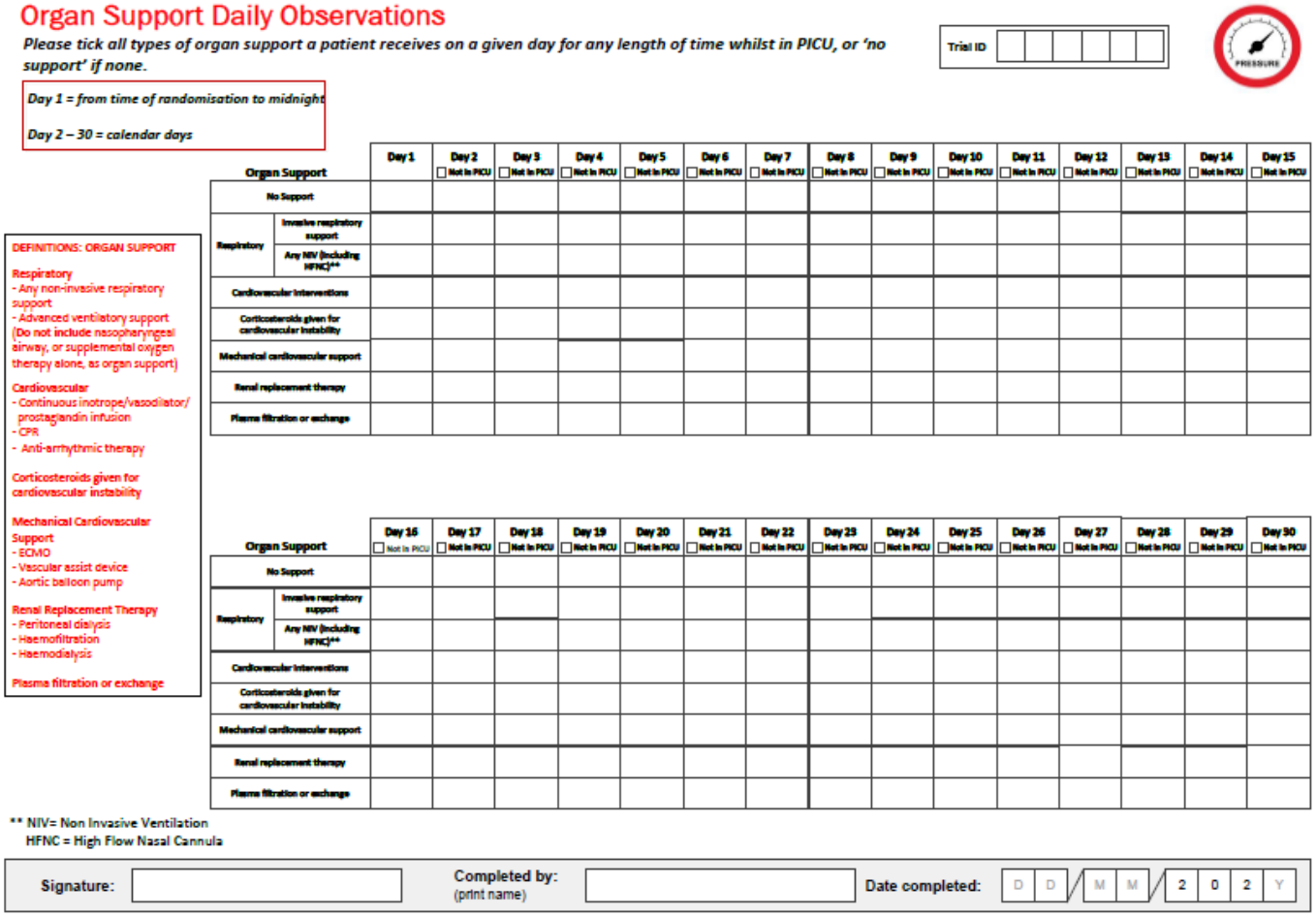


Organ Support Daily Observations

Please tick all types of organ support a patient receives on a given day for any length of time whilst in PICU, or 'no support' if none.

Trial ID

Day 1 = from time of randomisation to midnight

Day 2 – 30 = calendar days

Organ Support	Day 1	Day 2 ☐ Not in PICU	Day 3 ☐ Not in PICU	Day 4 ☐ Not in PICU	Day 5 ☐ Not in PICU	Day 6 ☐ Not in PICU	Day 7 ☐ Not in PICU	Day 8 ☐ Not in PICU	Day 9 ☐ Not in PICU	Day 10 ☐ Not in PICU	Day 11 ☐ Not in PICU	Day 12 ☐ Not in PICU	Day 13 ☐ Not in PICU	Day 14 ☐ Not in PICU	Day 15 ☐ Not in PICU
No Support															
Respiratory – Invasive respiratory support															
Respiratory – Any NIV (including HFNC)**															
Cardiovascular interventions															
Corticosteroids given for cardiovascular instability															
Mechanical cardiovascular support															
Renal replacement therapy															
Plasma filtration or exchange															

DEFINITIONS: ORGAN SUPPORT

Respiratory
- Any non-invasive respiratory support
- Advanced ventilatory support (Do not include nasopharyngeal airway, or supplemental oxygen therapy alone, as organ support)

Cardiovascular
- Continuous inotrope/vasodilator/ prostaglandin infusion
- CPR
- Anti-arrhythmic therapy

Corticosteroids given for cardiovascular instability

Mechanical Cardiovascular Support
- ECMO
- Vascular assist device
- Aortic balloon pump

Renal Replacement Therapy
- Peritoneal dialysis
- Haemofiltration
- Haemodialysis

Plasma filtration or exchange

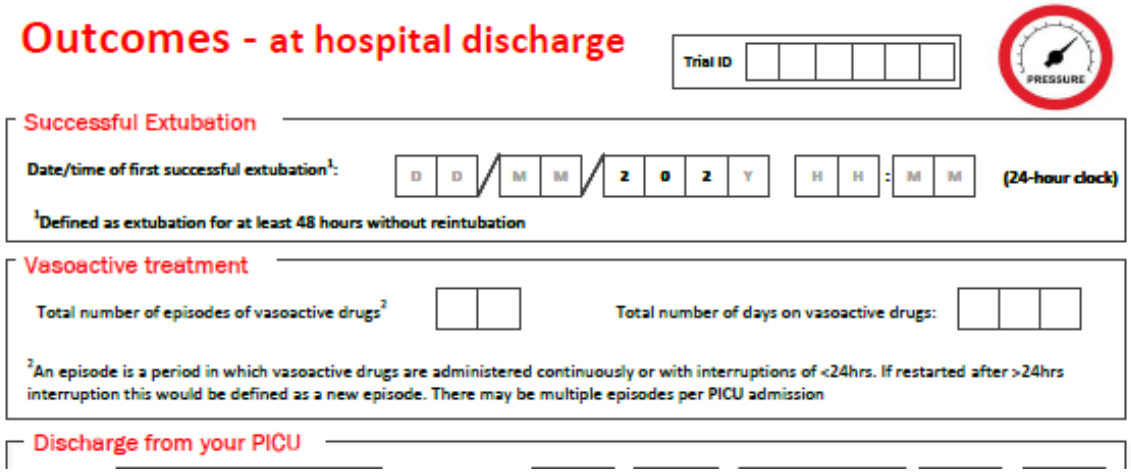
Organ Support	Day 16 ☐ Not in PICU	Day 17 ☐ Not in PICU	Day 18 ☐ Not in PICU	Day 19 ☐ Not in PICU	Day 20 ☐ Not in PICU	Day 21 ☐ Not in PICU	Day 22 ☐ Not in PICU	Day 23 ☐ Not in PICU	Day 24 ☐ Not in PICU	Day 25 ☐ Not in PICU	Day 26 ☐ Not in PICU	Day 27 ☐ Not in PICU	Day 28 ☐ Not in PICU	Day 29 ☐ Not in PICU	Day 30 ☐ Not in PICU
No Support															
Respiratory – Invasive respiratory support															
Respiratory – Any NIV (including HFNC)**															
Cardiovascular interventions															
Corticosteroids given for cardiovascular instability															
Mechanical cardiovascular support															
Renal replacement therapy															
Plasma filtration or exchange															

** NIV= Non Invasive Ventilation
HFNC = High Flow Nasal Cannula

Signature: | Completed by: (print name) | Date completed: D D / M M / 2 0 2 Y

Ensure any type of support received on any given day for any length of time is recorded from day 1 (randomisation – midnight) to day 30.

If patient is discharged from PICU and subsequently readmitted, select 'not in PICU' for those days and being recording again from readmission day



Outcomes - at hospital discharge

Trial ID

PRESSURE

Successful Extubation

Date/time of first successful extubation[1]: D D / M M / 2 0 2 Y H H : M M (24-hour clock)

[1]Defined as extubation for at least 48 hours without reintubation

Vasoactive treatment

Total number of episodes of vasoactive drugs[2]

Total number of days on vasoactive drugs:

[2]An episode is a period in which vasoactive drugs are administered continuously or with interruptions of <24hrs. If restarted after >24hrs interruption this would be defined as a new episode. There may be multiple episodes per PICU admission

Discharge from your PICU

The date of first successful extubation is defined as the patient being extubated for at least 48 hours without having to be reintubated

An episode is a period in which vasoactive drugs are administered continuously / with interruptions of <24 hrs.

The total number of days on vasoactive drugs should be at least the number of days ‘yes’ was recorded on the observations CRFs.

e-CRF

- Secure web-based data entry system (MACRO):
  - https://ctu.icnarc.org/macro/
  - Full audit trail – all changes to data are recorded against a named user
- Email pressure@icnarc.org to set-up an account
  - Individual must be listed on Delegation Log
- Data should be entered promptly

Any questions?