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POLAR trial
Positive end-expiratory pressure levels during resuscitation of preterm infants at birth

The POLAR Trial

Clinical Staff Orientation & Training Slides for Continuing Care Sites

Version 2.1: Dated – 30 April 2024

CPI: Prof David Tingay (david.tingay@rch.org.au)
International Trial Manager: Laura Galletta (laura.galletta@mcri.edu.au)

UK Clinical Lead: Prof Charles Roehr (charles.roehr@nbt.nhs.uk / charles.roehr@npeu.ox.ac.uk)
UK Trial Manager: Elizabeth Nuthall (elizabeth.nuthall@npeu.ox.ac.uk)

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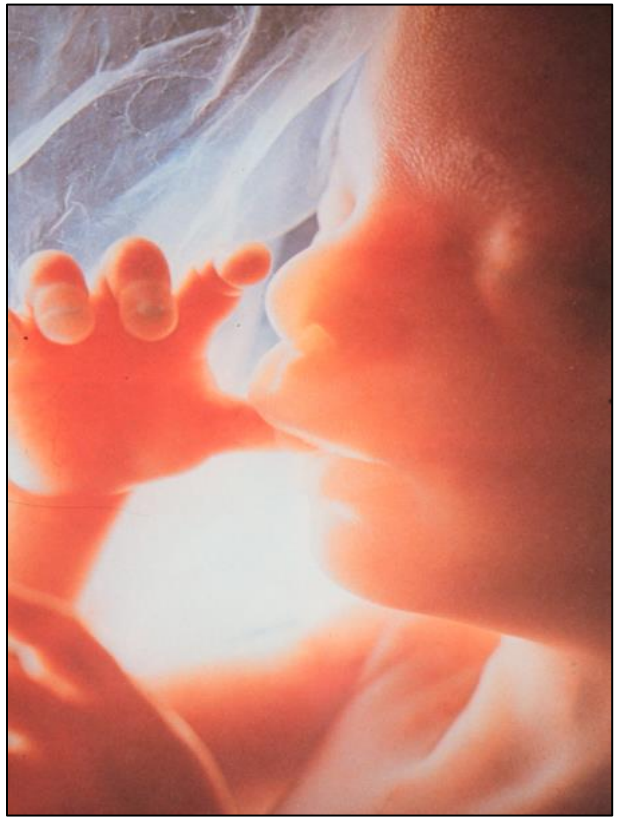
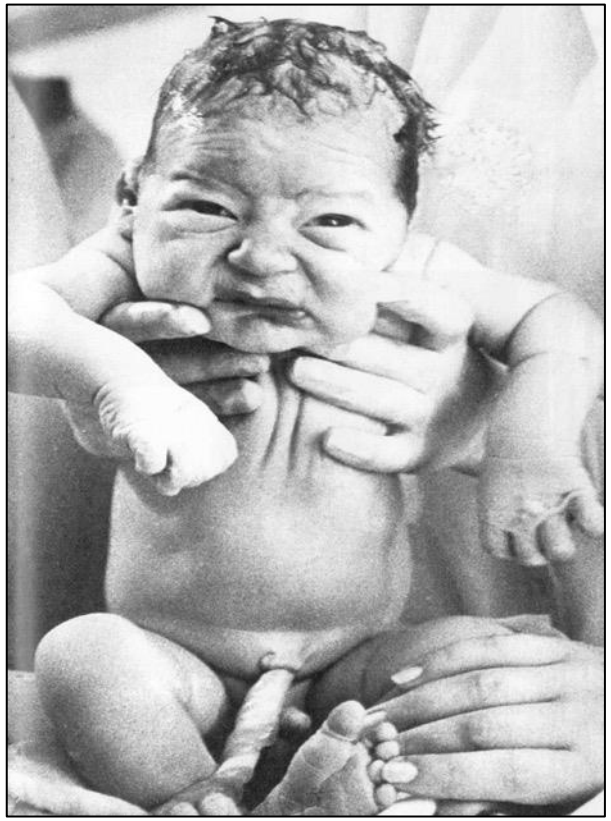
Physiology of the Respiratory Transition at Birth Rapidly Adapting to Air-Breathing





Initial Priorities:

- To clear fluid from airways and alveoli
- Establish Functional Residual Capacity
- Defend FRC during breathing

Then:

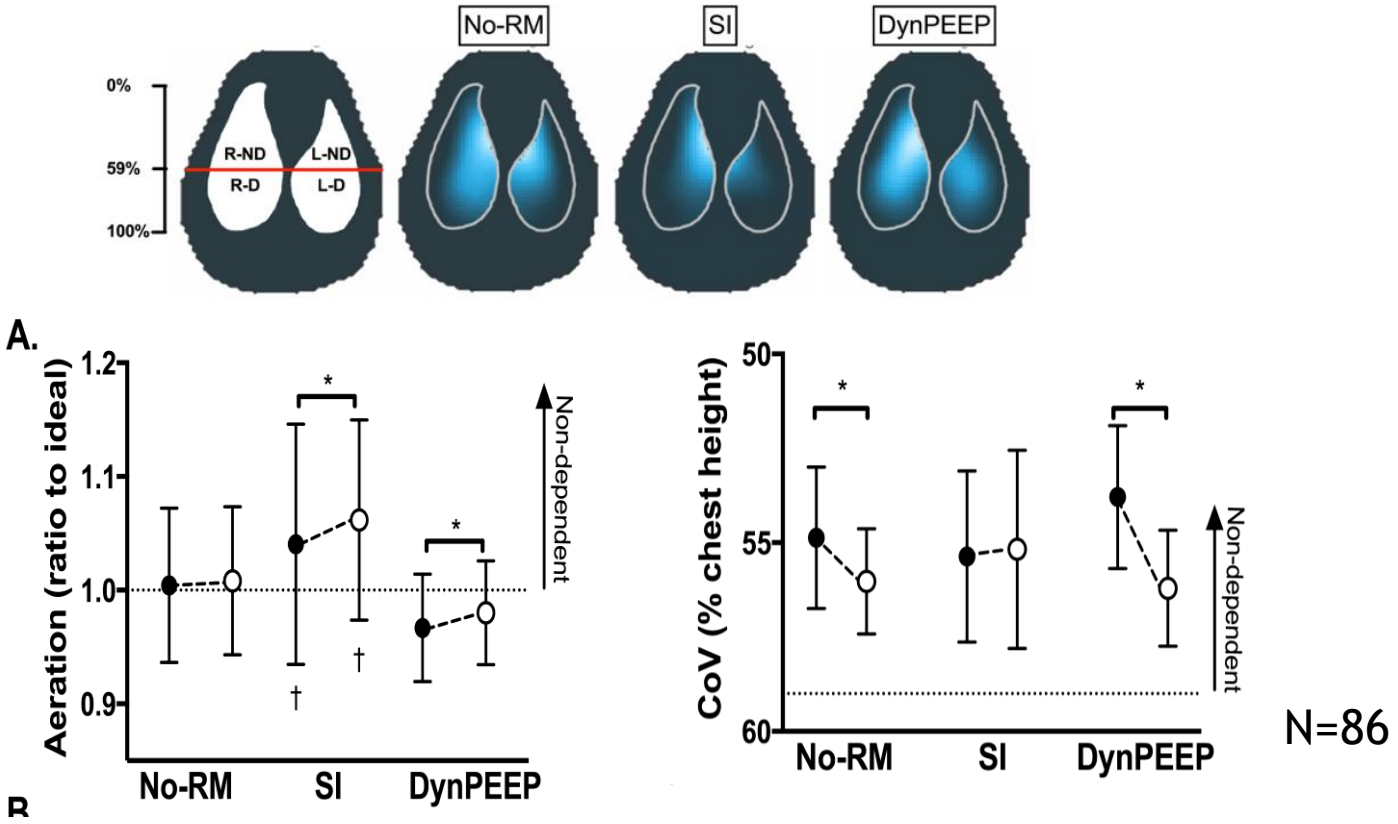
- Maintain tidal ventilation
- Preterm lung challenges

PIP and PEEP at birth > than PIP and PEEP to support the atelectatic surfactant-deficient lung.

Ref: Hooper, te Pas, Kitchen ADC F&N 2016

Dynamic PEEP reduces Lung Injury, improves Oxygenation

- **18 pre-clinical studies** demonstrated that PEEP is the most important pressure parameter at birth
- Dynamic PEEP superior to Static PEEP 5-8 cmH_2O or SI (n=7 studies)
- Dynamic PEEP synergistically improves clinical effect of surfactant (n=106 lambs)
- Initiation of VILI is reduced using DynPEEP



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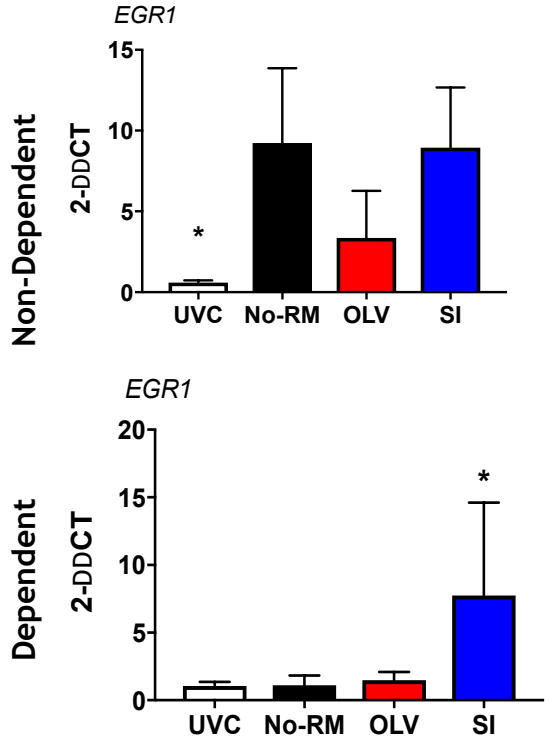

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Tingay AJRCCM 2019, Tingay Ped Res 2014, Tingay AJRMCB 2016, Tingay Ped Res 2016, Tingay AJP_Lung 2017

What is “Dynamic PEEP”?

- There is no evidence to justify any PEEP level used in the NICU or DR
- Too low a PEEP will cause harm – ↑ WOB, ↑ hypoxia and ↑ airleak risk
- Too high a PEEP will cause harm – ↑ WOB, ↑ hypoxia and ↑ airleak risk

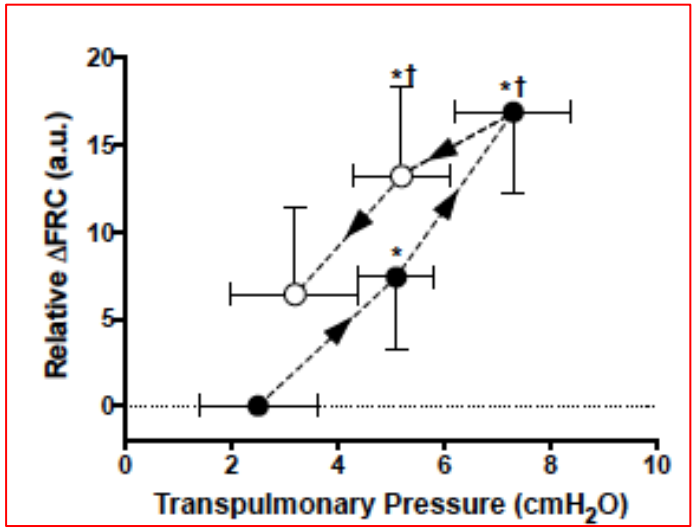
- The PEEP level the lung needs at any point in time is known only to the patient
- Nearly all NICU use a narrow and pre-defined PEEP approach

- Why not titrate PEEP levels to clinical need?
- Un-aerated/atelectatic lung needs a higher PEEP than a recruited and aerated lung (hysteresis)
- Increase PEEP in a step-wise manner and assess clinical response
  - Only increase PEEP if safe to do so
  - Only decrease PEEP when clinical response has been achieved

Dynamic PEEP Strategies in Preterm Infants: Human experiences during NIV

Bhatia J Ped 2018 (RWH)

- N=20 infants <18 hr old on CPAP
- PEEP 5/6 – 8 – 10 – 8 – 6 cmH_2O
- All infants: ↑PEEP = ↑ FRC
- 50% maintained FRC with PEEP 10 to 8; 50% lost FRC with PEEP wean



Martherus Frontiers 2019 (Leiden/Germany)

- N=104 infants <29/40
- Observational study
- NRP 5-8 cmH2O vs Bellavista inc in flow (max PEEP 35 cmH2O) if clinically deteriorating
- Higher PEEP approach:
  - Reduced need for Mechanical Ventilation <72 hr: 26% vs 56%
  - PTx increased: 19% vs 4%
  - No difference in SpO_2 in DR but FiO_2 higher in NRP group

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Dynamic PEEP Strategies in Preterm Infants: Human experiences during NIV

Kanaan BMC Ped 2020 (Paris)

- NRP PEEP 5 cmH_2O (n=91) vs SI+Dynamic PEEP (n=72)
- GA <32/40
- Observational study (historical control)
- Maximum PEEP = 15 cmH_2O
- PEEP weaned if FiO_2 <0.4
- <29/40 (n=48 & 42) DynPEEP+SI reduced:
  - Mechanical Ventilation <72 hr: 71% vs 92%
  - Intubation in DR: 55% vs 90%
  - Surfactant: 12% vs 54%
  - BPD: 5% vs 23% (?)
  - No difference in mortality or PTx (2-5%)
- Dynamic PEEP in the DR is feasible at PEEP <15 cmH_2O

$PEEP_{MAX}$ level (n=72)	5	8	10-12	15
	30%	20%	36%	14%

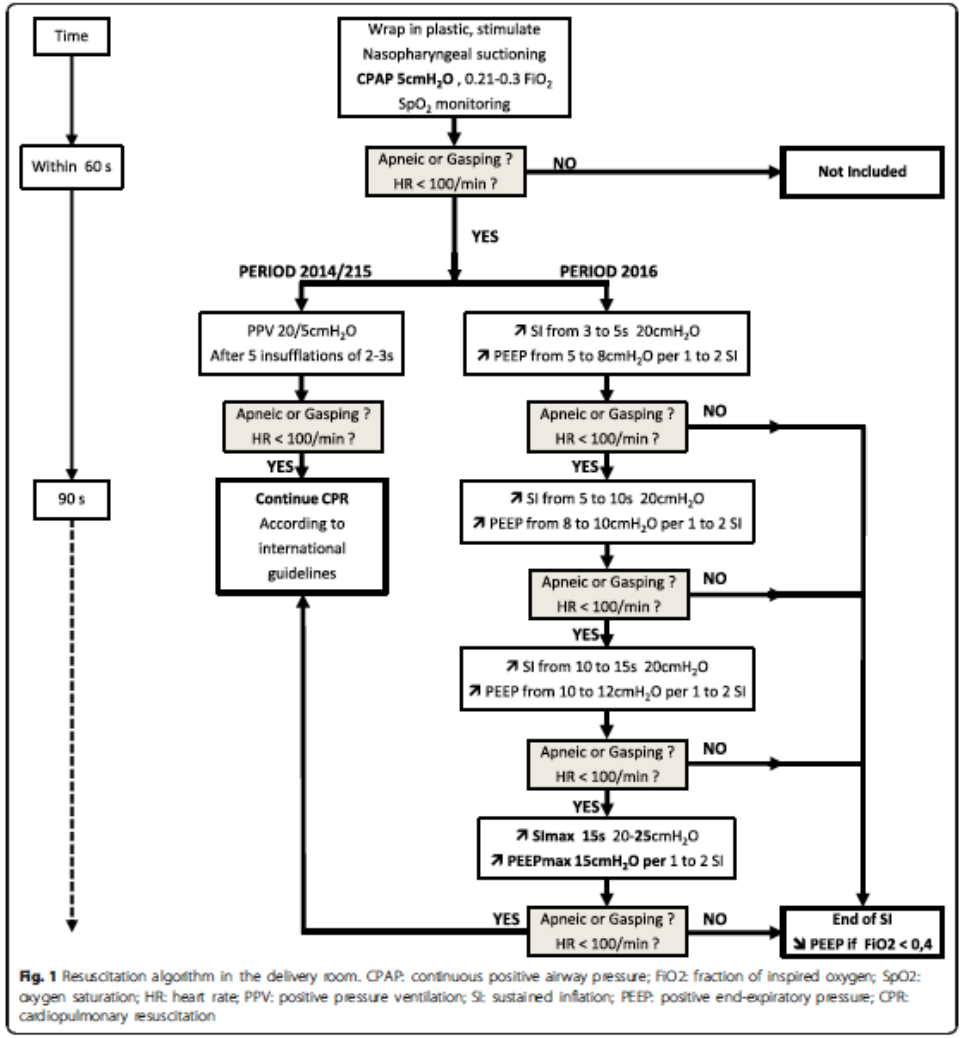

Fig. 1 Resuscitation algorithm in the delivery room. CPAP: continuous positive airway pressure; FiO2: fraction of inspired oxygen; SpO2: oxygen saturation; HR: heart rate; PPV: positive pressure ventilation; SI: sustained inflation; PEEP: positive end-expiratory pressure; CPR: cardiopulmonary resuscitation

Trial Hypothesis:

That a high dynamic PEEP strategy (PEEP 8-12 cmH_2O individualised to clinical need) as compared to static PEEP (5-6 cmH_2O), will:

1. Increase survival without BPD; and

2. Reduce rates of common neonatal morbidities.

Trial Aims:

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Positive end-expiratory pressure levels during resuscitation of preterm infants at birth

AIM: To establish whether a high, dynamic PEEP strategy compared with a standard PEEP strategy during stabilisation at birth increases survival without BPD in preterm infants between 23-28+6 weeks PMA.

P: 906 extremely preterm infants born <29 weeks PMA

I: **High, Dynamic PEEP** (titrated 8-12 cmH_2O) to support the lung during stabilisation at birth

C: **Standard (NRP), static PEEP** (5-6 cmH_2O)

O: Composite of death/BPD at 36 weeks PMA (ORT): Reduction 52% to 41% (90% power)

T: Estimated 5 year recruitment, planned 2 year follow up

Secondary Outcomes: Reduced rates of short and long-term neonatal morbidities, including **failure of non-invasive support in the first 72 hours of life** and **air leaks.**

Trial Design:

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Positive end-expiratory pressure levels during resuscitation of preterm infants at birth

- Randomised, unblinded intervention (ITT)
- Stratified by GA (23-25 wk; 26-28 wk GA)

- Inclusion: Needing resuscitation within GA range
- Exclusion: Pulmonary hypoplasia, major congenital anomalies

- Antenatal or deferred consent
- Standardised criteria for intubation during the intervention period in DR
- Recommended criteria for immediate post-resuscitative care and intubation/extubation in first 72 hours
- *DCC, surfactant protocols and most other DR interventions at site discretion*

Trial Intervention:

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- **Study intervention period**
  - Mask on face until 20 minutes of age
  - Group separation (by randomised PEEP) to be maintained

Intervention Period = 20 minutes maximum or clinical stability is reached

- In **both arms** PPV can be commenced at any stage

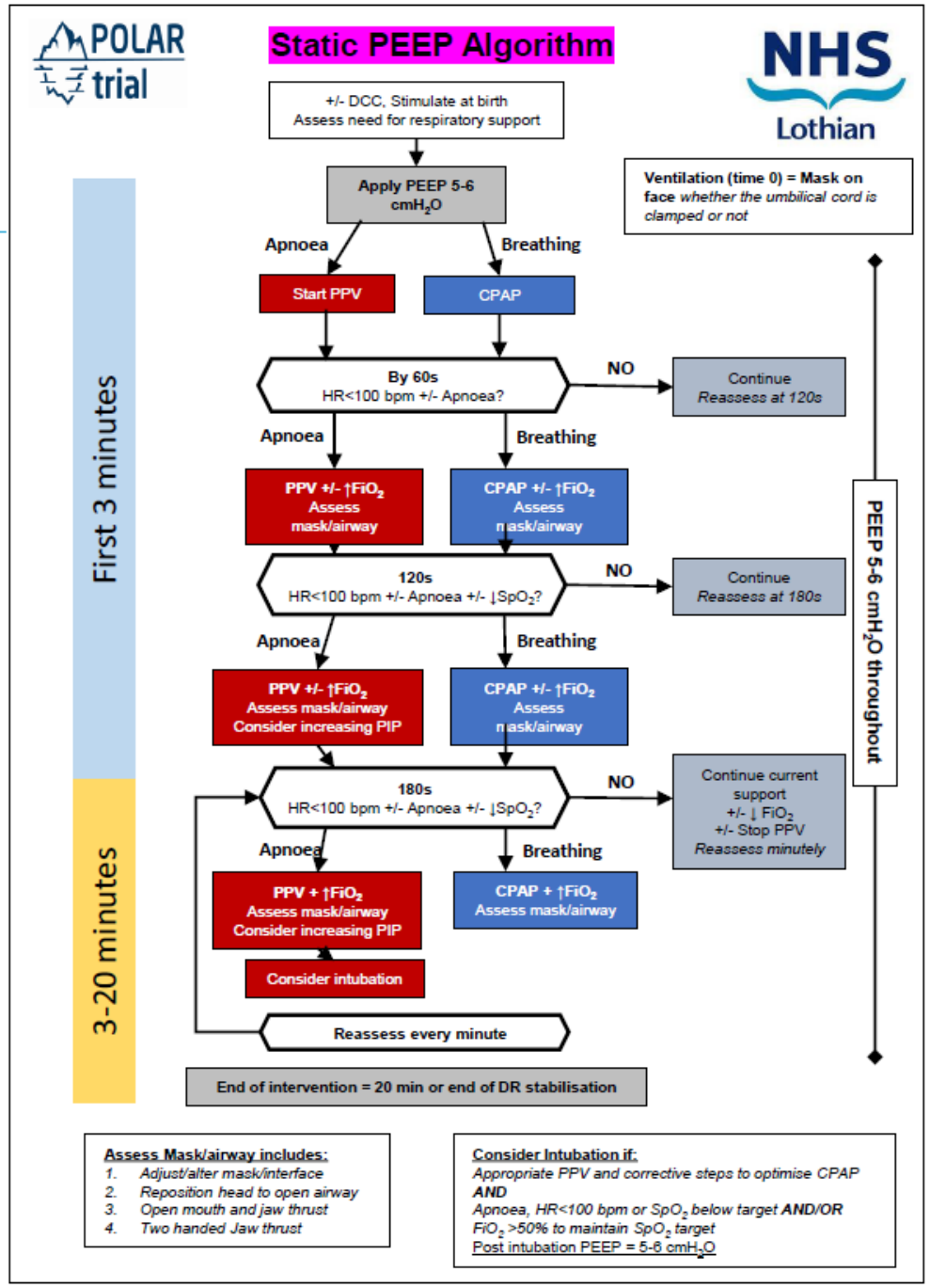
- Cardiorespiratory stability assessed every 60s

  Pulse oximetry can be used at anytime
  But oximetry should only be used before 3 mins if reliable signal

Standard Group: Static PEEP

- Commence PEEP 5-6: reassess
- If apnoea/HR<100: ventilatory corrective steps +/- commence PPV
- Reassess at least every minute

- Consider ETT if PPV and:
  - HR<100 or
  - apnoea or
  - FiO_2 >50% >5mins…
- If ETT cont. PEEP 5-6 cmH_2O



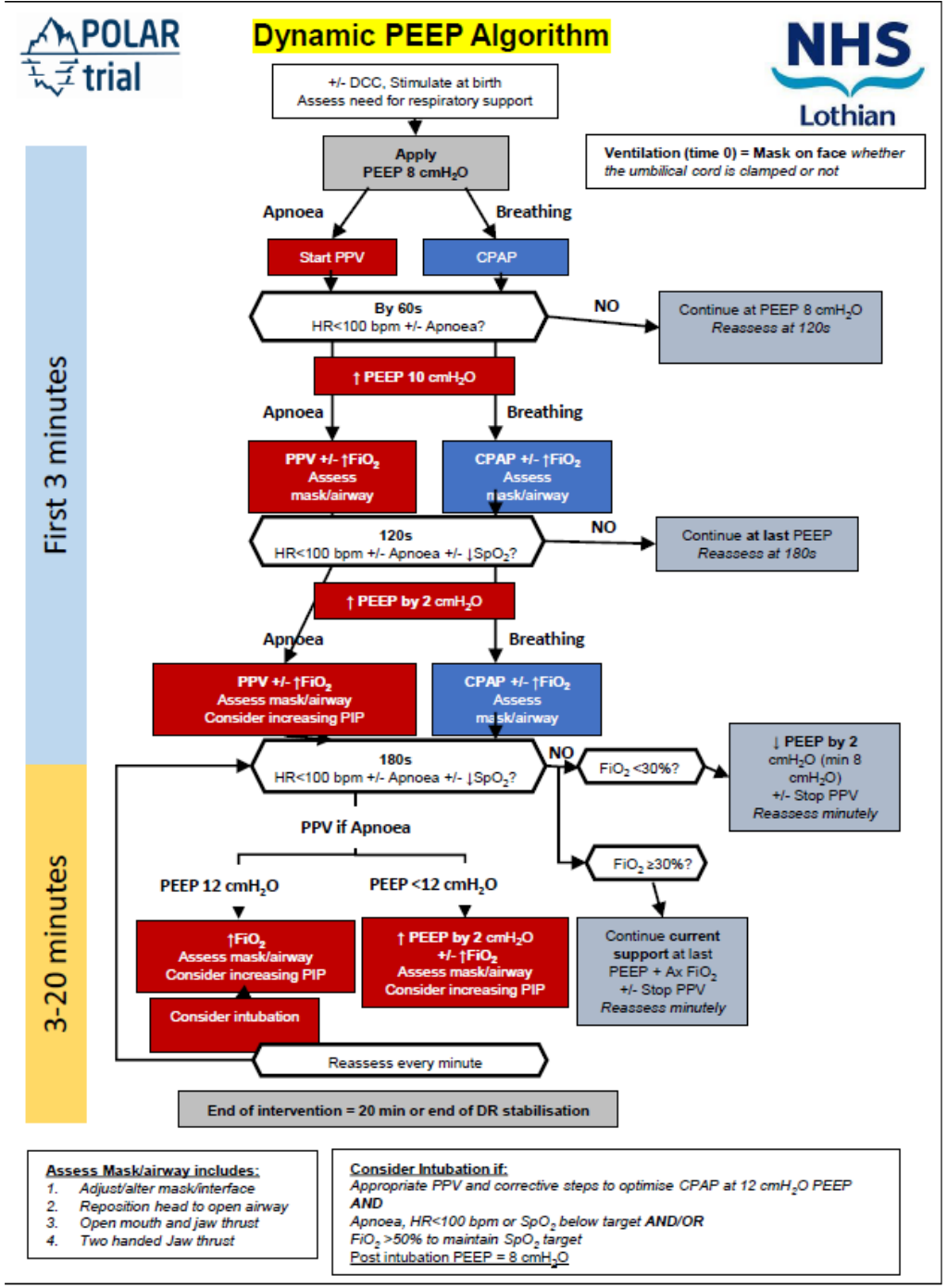
EDIN Site-Specific Static Algorithm - Version 1.0 was approved by the POLAR Trial Steering Committee on: 21 Feb 2024

Intervention Group: Dynamic PEEP

- Commence PEEP 8, reassess…
- Good resp effort + HR >100 = cont. PEEP 8
- If not: ventilatory corrective steps + increase PEEP to 10 +/- PPV

- Reassess at least every minute
- Good resp effort + HR >100 cont. set PEEP
- If not: increase PEEP by 2, max 12cmH_2O

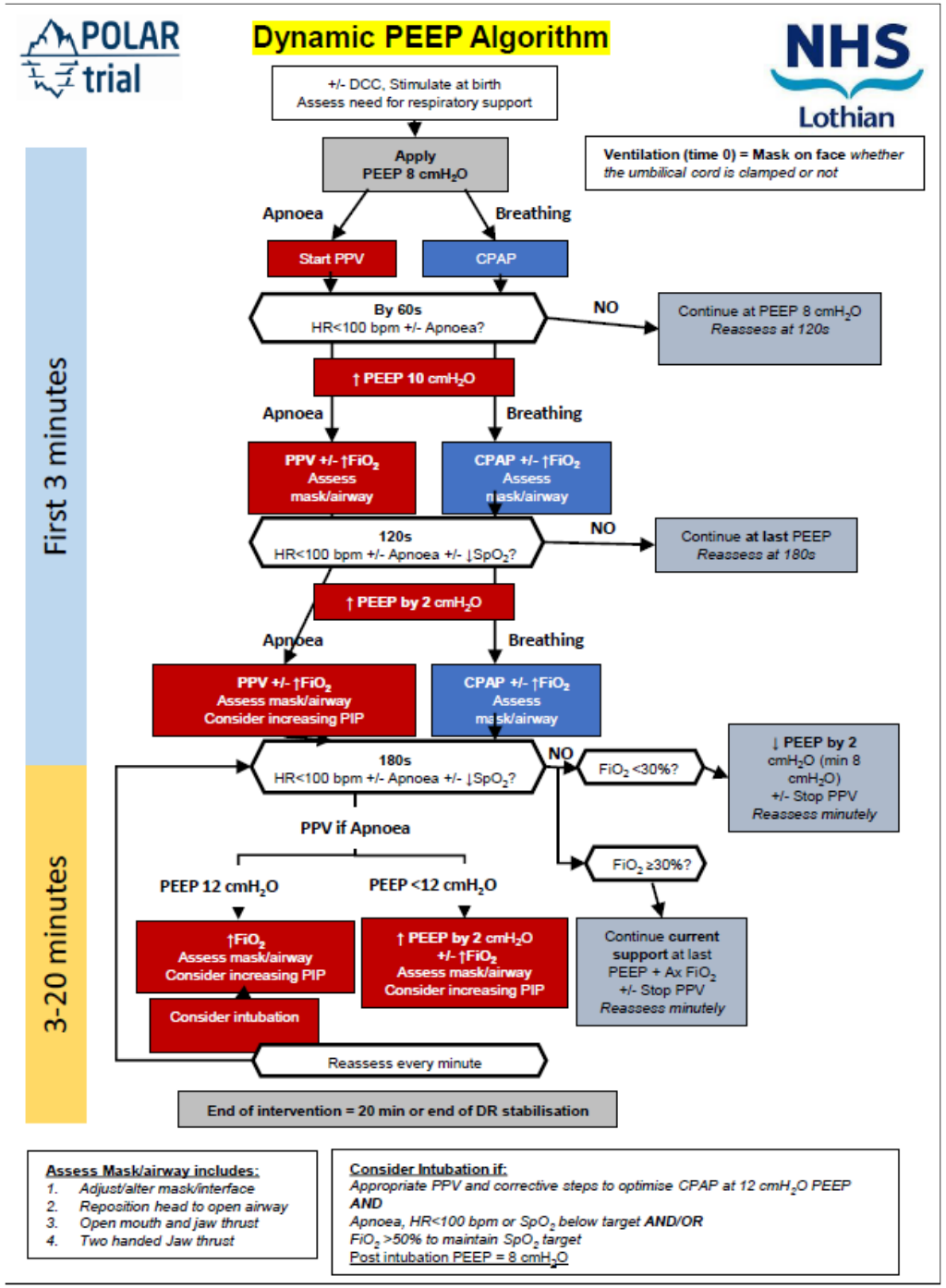
- Continue minutely reassessment



EDIN Site-Specific Dynamic Algorithm - Version 1.0 was approved by the POLAR Trial Steering Committee on: 21 Feb 2024

Intervention: Dynamic PEEP

- Consider ETT if PPV *and* PEEP 12 *and*:
  HR<100 or
  apnoea or
  FiO2 >50% >5mins
- If HR>100 + FiO_2 <30% for 1min;
  decr. PEEP by 2 (min. 8 cm H_2O)
- <u>If intubate in first 20 min use PEEP 8</u>
- PEEP >8 only used in DR



EDIN Site-Specific Dynamic Algorithm - Version 1.0 was approved by the POLAR Trial Steering Committee on: 21 Feb 2024

Post Intervention DR and NICU care after 20 mins:

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- PEEP levels can be applied as per Site Practice after 20 mins
- **Recommended** that final PEEP level in use during intervention be continues
- **Recommended** that infants remain in allocated treatment group if clinically responding
- We will revert to 5-6 cm of PEEP

- If already standard practice at a Site the following are allowed:
- Static Group: PEEP up to 8-10 cmH_2O to prevent intubation
- Dynamic Group: Weaning PEEP <8 cmH_2O if infant stable and FiO_2 <30%
- Dynamic PEEP algorithm is NOT permitted after 20 mins

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Intubation Criteria first 72 hours:

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- After the 20 min intervention period
- Maximal non-invasive support plus ≥1 of:

  - Apnoea - >6/6hrs requiring stimulation or >1 PPV/24hrs
  - Sustained oxygen requirement: discretionary at 30%, mandatory at your sites guidelines
  - Respiratory acidosis: pH<7.2 and CO_2 >65 mmHg -8.66 KPa
  - Emergency intubation

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Extubation Criteria first 10 days:

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- Should be attempted within 24 hours if:

  MAP ≤8 and

  CO_2 ≤55 and

  pH ≥7.25 and

  FiO_2 ≤40 and

  adequate respiratory effort

- Extubation can be attempted from higher settings
- Post extubation support at site discretion

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Safety Monitoring – AEs & SAEs:

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- Protocol-defined AEs and SAEs require reporting to the Sponsor c/o Primary Recruiting Site

Protocol-defined AEs:

Adverse Event Definition	Reporting Time Frame
Oxygen requirement of FiO_2 ≥50% for 3 hours or more*	Within the **first 72 hours** of life
Infant requiring FiO_2 >30% or mechanical respiratory support using an endotracheal tube	Respiratory support assessment only at **day of life 28**

Protocol-defined SAEs:

Serious Adverse Event Definition	Reporting Time Frame
Any Death	Within the **first 72 hours** of life
Pulmonary Haemorrhage	Within the **first 72 hours** of life
Grade 3 or 4 IVH or PVL	Head ultrasound findings within the **first 10 days of life** (report based only).
Pneumothorax and/or pneumopericardium. These will be supplemented by data on: a) Any chest tube b) Need for new chest tube after arrival in NICU	Radiographic or lung ultrasound evidence within the **first 10 days of life.**
Administration of epinephrine or use of chest compressions	Within the **first 72 hours** of life

All additional AEs/SAEs deemed **related or possibly related** to the intervention must also be reported, ***up until*** 36 Weeks PMA

Please report all occurrences to the Primary Recruiting Site

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Sims

Training and Documentation

Training on PEEP Delivery

- At each site, the Site PI or his/her delegate will be responsible for delivery of local training. Specific training will be required for all clinicians who will be administering both the static and/or dynamic PEEP resuscitative interventions.
- Training activities include the following:
  - Reading the relevant section/s of the POLAR Protocol relating to your trial-related duties and/or functions, as applicable
  - Review of the Site Initiation Presentation (slide set)
  - Watching the POLAR training videos [see below Section 5.2]
  - Review Section 8.0 of the POLAR Manual of Procedures (MOP) document: *Delivery Room Procedures*
  - Attending local in-service session on infant resuscitation *(if applicable at your centre)*.
- Upon successful completion of all the training activities listed above, clinicians will be required to complete the PEEP Training Attestation Checklist* to document their training. The Training Attestation form only needs to be completed by the clinicians who will be delivering the intervention.

Accessing the POLAR Trial Training Videos

- Access to the training videos is via the POLAR Trial website:

1. Navigate to the POLAR Trial website at www.POLARTrial.org.au
2. Click on the ‘Members Portal’ tab on the top right-hand side of the menu bar
3. Please ensure you have your Member's Portal credentials handy to log into this area
4. Log into the Members Portal

- Click on each video to view the training

To consent I need from you:

1) Your CV and GCP forms (I have many of these, so don't need to send again if I have them previously)
2) Your signature on the Site delegation log electronically -save as new name and it should let you sign electronically
3) Site training log signature as above
4) Your Training attestation form

5) A few additional people
    1) Redcap EDC access form

Trial Monitoring:

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- Data Safety Monitoring Committee (DSMC) – Prof Richard Polin (Expert Neonatologist), Prof Peter Rimensberger (Expert Neonatologist), Dr Trisha Prentice (Bioethicist and Neonatologist), Ms Sabine Braat (Statistician), Xiaofang Wang [independent stats])
- Interim safety analysis at 50, 100, 302, 450, 604 infants enrolled *(50, 100 and 302 baby interim safety analyses already completed – no safety concerns identified)*
- Medical Monitoring of AEs/SAEs
- Unblinded DR Intervention Compliance Monitor
- Study Endpoint Adjudication Committee (SEAC) – monitoring, review and coding of causality of all Mortality events reported

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Primary Recruiting sites in the UK:

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1. **Southmead Hospital, Bristol:** PI = Prof Charles Roehr (charles.roehr@nbt.nhs.uk)
2. **Leicester University Hospital/Leicester Royal Infirmary:** PI = Dr Joe Fawke (joe.fawke@uhl-tr.nhs.uk)
3. **James Cook University Hospital:** PI = Dr Prakash Loganathan (pkannanloganathan@nhs.net)
4. **Birmingham Heartlands Hospital:** PI = Dr Harsha Gowda (harsha.gowda1@nhs.net)
5. **Royal Hospital for Children Glasgow:** PI = Dr Joyce O'Shea (joyce.oshea@ggc.scot.nhs.uk)
6. **University Hospital Wishaw:** PI = Dr Karen McCall (karen.mccall@lanarkshire.scot.nhs.uk)
7. **Edinburgh Royal Infirmary:** PI = Dr David Quine (david.quine@nhslothian.scot.nhs.uk)

→ Approached 50 Continuing Care Sites (CCS) (NHS Trusts) across England and Scotland to support collection of primary endpoint data from POLAR enrolled infants repatriated across these 50 centres.

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Trial Support - What is needed from Continuing Care Sites (CCS):

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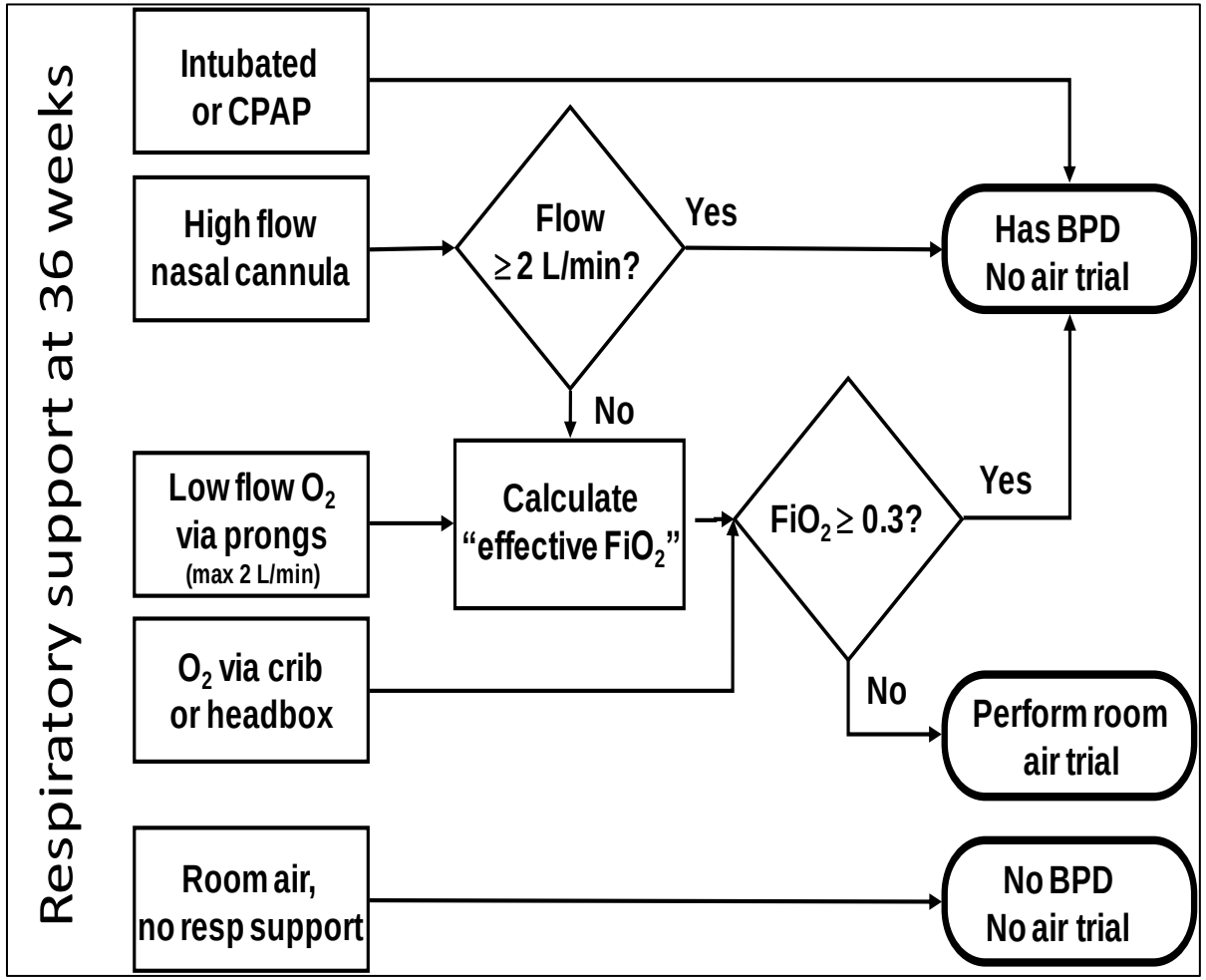
1. Need CCS to facilitate the collection of primary endpoint data for POLAR consented and enrolled babies, who are routinely transferred to CCS's as part of standard practice, prior to 36-Week CGA
2. Undertake a BPD Assessment (+/- Oxygen Reduction Test (ORT)) at 36-week CGA for POLAR babies transferred into your care, if assessment not already completed by Primary Recruiting Site
3. Complete of the POLAR Transfer Pack (i.e. paper CRF) and email completed Transfer Packs back to **primary recruiting site (via NHS email accounts)**
4. Identify any protocol-defined AEs/SAEs and **alert these events to the primary recruiting site** (via NHS email) for onward reporting to the Sponsor (rare occurrence)
5. **Alert the primary recruiting site of any deaths** in any POLAR enrolled infants (via NHS email) that may occur, for onward reporting to the Sponsor.

36-Week CGA BPD Assessment:

Material Check:
- Manual of Procedures (MoP) Document
- CRF Completion Guidelines
- Access to POLAR Main Study Database (REDCap)

- Assessment of BPD status (modified Walsh Test +/- standard oxygen reduction test) performed on the date determined to be 36+0 to 36+6 weeks CGA:
  - If the BPD assessment cannot be performed at ~36 weeks CGA, recommended that it be performed ASAP after 36+6 weeks CGA
- Assessment should be performed in conjunction with clinical assessment of BPD for local or regional reporting practices (e.g., VON, ANZNN)
- If regional reporting requires additional/alternative methods of assessing BPD (e.g., the Shift Test), these should still be conducted



Transfer Pack / Paper CRF:

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CONTINUING CARE SITES TRANSFER PACK

INTRODUCTION:

Welcome to the POLAR Trial!
Thank you for facilitating the 36-Week BPD Assessment of trial participants.

Further information regarding the trial can be found via our website: www.POLARTrial.org.au

Any questions regarding completion of this Case Report Form (CRF) can be directed to the Primary Site or contact the Trial Coordinating Centre at: POLAR@mcri.edu.au

TABLE OF CONTENTS

FORM COMPLETION INSTRUCTIONS

Sections 1 and 2:	To be completed by the Primary enrolling Site upon transfer of participant to Continuing Care Site.
Section 3, 4 and 5:	To be completed by the Continuing Care Site.

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Transfer Pack / Paper CRF Cont'd:

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SECTION 3: 36-Week BDP Assessment CRF

WHAT TO DO

- Perform this assessment on a date determined to be **between 36+0 to 36+6 weeks corrected gestational age.**
- Use figure 1 below, starting with the level of respiratory support being given, to determine whether a room air trial (oxygen reduction test) is required.
- If indicated, determine the "effective FiO_2" using the following website: http://hdl.handle.net/1802/3212, and downloading the **StopFiO2_js.htm** file. Enter the baby's current weight, oxygen concentration (as a percentage) and gas flow rate (litres per minute). Enter the "effective FiO_2" into figure 2 below.
- If required, carry out a room air trial/oxygen reduction test (instructions below) and complete the relevant sections on the *36-Week Assessment* and *36-Week Room Air Trial* forms below.

Figure 1

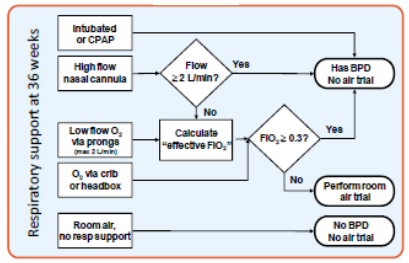

Figure 2

Calculation of effective FiO_2

Current weight ☐☐.☐ kg

Actual FiO_2 (enter as percentage) ☐☐☐ %

Gas flow rate (note max = 2L/min) ☐.☐ litres per minute

Calculate

Effective FiO_2 (as percentage) ☐☐☐ %

36-Week Assessment

Date of Assessment ☐☐ DD ☐☐ MM ☐☐☐☐ YYYY

Time of BPD Assessment (24 hr clock) ☐☐ HH : ☐☐ MM

Type of respiratory support *(Choose one)*	○ Intubated	*If yes, no further data needed*
	○ Nasal CPAP	*If yes, no further data needed*
	○ High flow nasal cannula	*If HFNC:* FiO_2 ☐.☐ (write as decimal) Flow rate ☐.☐ litres per min *If HFNC ≥2 L/min no further data needed*
	○ Low flow prong oxygen	FiO_2 ☐.☐ (write as decimal) Flow rate ☐.☐ litres per min *If low flow prong oxygen*
	○ Crib or head-box oxygen	FiO_2 ☐.☐ (write as decimal) *If crib or head box oxygen*
	○ No resp support, no oxygen	*If yes, no further data needed*
Room air trial required?	○ Yes ○ No	*If yes, follow instructions overleaf*

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SECTION 4: Oxygen Reduction Test (ORT)

HOW TO PERFORM THE OXYGEN REDUCTION TEST (**ONLY** IF EFFECTIVE FiO_2< 30%)

- Conduct the trial when the infant is in quiet sleep if possible. Time the trial such that it will not coincide with the need to offer oral feeds, or other planned interventions.
- Continuously monitor the oxygen saturation (SpO_2) and pulse rate using a standard oximeter with alarms set at SpO_2 89% (lower) and 95% (upper)
- For the purposes of this oxygen reduction test, the acceptable SpO_2 target range will be 90-94% before the trial.
- During the physiological evaluation, all infants should **ONLY** continue to the next FiO_2 or gas flow reduction step if SpO_2 is >=90% during the 5-minute monitoring phase.
- **STOP CRITERIA:** Immediately discontinue if SpO_2 are <90% for 5 continuous minutes, or <80% for 15 seconds or more (good quality oximetry signal) or they become apnoeic or bradycardic for >20 s. The infant should immediately be placed back into their baseline oxygen concentration and/or flow settings and the Oxygen Reduction Test recorded as a **FAIL**.
- **PASS** = maintenance of SpO_2 within the target range in room air for 30 minutes from the time of cessation of oxygen therapy.
- **FAIL** = Failure is defined as SpO_2 <90% for 5 continuous minutes, or <80% for 15 seconds or more (good quality oximetry signal) or apnoea or bradycardia for >20 seconds.
- Oxygen therapy +/- respiratory support should thereafter be reinstituted as per their baseline, irrespective of the test outcomes.
- The results of the room air trial should be shared with the treating clinicians and documented clinically as per your local guidelines/practice.

METHOD

If on nasal cannulae (high or low flow) with oxygen blender:
Make stepwise 2% reductions in FiO_2 every 5 minutes, aiming to reach air within 20 minutes. If SpO_2 is still within the 90-94% target range, then stepwise reduce gas flow gradually to zero (0.5 LPM decrements until flow 0.5 LPM, then 0.1 LPM reductions). If SpO_2 remains within the target range, gently **remove the prongs** from nares (but not face) and monitor for 30 minutes in room air (or 15 minutes if SpO_2 ≥96% for 15 continuous minutes).

If on low flow nasal cannulae oxygen (100% oxygen concentration, no blender):
Make stepwise reductions in the gas flow every 5 minutes aiming to reach zero flow within 20 minutes (e.g. 0.5 LPM increments until flow 0.5 LPM, then 0.1 LPM reductions). If flow metre allows further wean, decrease flow rate (e.g. in 0.02 LPM increments) every 5 minutes to lowest deliverable flow rate. If SpO_2 remains within the target range, gently **remove the prongs** from nares (but not face) and monitor for 30 minutes in room air (or 15 minutes if SpO_2 >=96% for 15 continuous minutes).

If receiving oxygen via isolette (crib or headbox):
Make stepwise reductions in FiO_2 by ~2% every 5 minutes, aiming to reach air within 20 minutes. Monitor for 30 minutes in room air (or 15 minutes if SpO_2 >=96% for 15 continuous minutes).

36-Week Room Air Trial

Actual FiO_2 at start ☐.☐ (write as decimal) Effective FiO_2 at start (from previous page) ☐.☐ (write as decimal)

Lowest gas flow reached ☐.☐ litres per min Lowest actual FiO_2 reached ☐.☐ (write as decimal)

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SECTION 5: Form Completion

To be completed by the Continuing Care Site/Receiving Hospital when completing this Form

Name of person completing this form:	
Name of Hospital:	
Signature:	
Date of Completion: *(dd/mmm/yyyy)*	

WHAT TO DO NOW

1. Please scan and return completed forms to the POLAR primary enrolling site listed on the Cover Page of this Transfer Pack (page 1)

THANK YOU FOR COMPLETING THIS FORM

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Thank you for supporting this promising trial!

More information can be found on the Trial's website:
www.POLARTrial.org.au

Questions: laura.galletta@mcri.edu.au OR POLAR@mcri.edu.au

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