Supplemental Online Content

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This supplementary material has been provided by the authors to give readers additional information about their work.

eAppendix 1. Clinical management appendix

Trial: CORSAD

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The aim of The Clinical Management Appendix is to provide support for clinical management and a standard that centres can adhere to. We recognise that individual units may have specific guidelines that do not agree on all these points. Centres participating in the trial need to forward and discuss these differences before enrolling patients. New routines, guidelines or results from trials, during the study period also need be discussed before changing management. The Appendix will thus be updated during the trial. Conflicts on clinical management will be referred to the Data Monitoring Committee and/or local ethics committee if judged by the steering committee to be important.

Antenatal management

Antenatal steroids

Background: Antenatal corticosteroid treatment has been shown in meta-analysis from 2006 to be beneficial. This has been discussed and also confirmed for extremely premature infants.[1-3] A second course of antenatal steroids if delivery is delayed for more than 7 days after initial treatment has been discussed but guidelines are not clear.

Recommendation: Antenatal steroids should be given when possible. Time and dose by local guidelines. The optimal delivery to treatment interval should be 24 h and less than 7 days.[4]

Chord clamping

Delayed chord clamping

Background: There Cochrane review by Rabe et al recommend delayed cord clamping for 30-180 s but the results were based on few preterm infants. [5] European RDS Guidelines recommend: if possible delaying clamping for at least 60 s with the baby held below the mother.[4] The Swedish national guidelines on extremely preterm infant recommend a 45-60 s delay.[4] The 2015 ILCOR guidelines suggest delayed cord clamping when the preterm infant does not require immediate resuscitation after birth. The guidelines suggest against routine cord milking for premature infants.[6]

Recommendation: Delayed cord clamping is recommended when possible but cord milking is not recommended. Follow local routine. Not reported.

Initial stabilisation: monitoring, temperature and suctioning

Monitoring and cord blood analysis

Background: ILCOR guidelines recommend placing a pulse oximetry on the right hand to monitor SpO2 and pulse. However recent studies have showed that the ECG measures heart rate more reliable and faster than the pulse oximetry .The 2015 ILCOR guidelines suggest that ECG can be used to provide a rapid and accurate estimation of heart rate. [7] [8]

Recommendation: During resuscitation SpO2 (right wrist) and HR by ECG are recommended. Arterial and venous cord blood analysis should be recorded when available.

Temperature maintenance

Background: Strategies to maintenance body temperature has been reviewed by McCall in a meta-analysis.[9] Active prevention should be used even if the long term consequences have not been studied. European guidelines recommend plastic bags or occlusive wrapping under radiant warmer in infants < 28 w.[4] The 2015 ILCOR guidelines states that admission temperature of newly born non-asphyxiated infants is a strong predictor of mortality and morbidity at all gestations. It should be recorded as a predictor of outcomes as well as a quality indicator.

Recommendation: Follow local routine and report temperature measured within 15 min of NICU arrival. Humidification of fresh gas flow during resuscitation is allowed, if used for both systems.

Suctioning of secretions

Background: Clear excessive secretions from mouth and nose when needed

Recommendation: Follow local routine. Not recorded.

Initial stabilisation: Oxygen, CPAP, PPV and intubation

Oxygen

Background: 65-100% oxygen is not recommended because of higher mortality over ambient air.[10] The 2015 ILCOR guidelines recommend initiating stabilisation with 21-30%in infants born <35 w GA.[6]

Recommendation: Resuscitation should start at 21-30% oxygen. Pure oxygen should not be used and reported as protocol violation. Adjustment of O2 during initial stabilisation should be done after securing adequate ventilation and absence of bradycardia. Subsequent adjustment of O2 by local protocol and SpO2 target of 90-95% at ten minutes of age.

PPV and CPAP for the two resuscitation systems

Background CPAP level: The 2015 ILCOR guidelines suggest that, for spontaneously breathing preterm infants with respiratory distress requiring respiratory support in the delivery room, initial use of CPAP should be used rather than intubation and IPPV. European RDS guidelines recommend stabilisation with CPAP of at least 5-6 cm H2O for spontaneous breathing infants.[4] This is grade A recommendation but the referred trials does not compare different CPAP levels.

Background PPV level: European RDS guidelines does not give recommendation on PPV levels. ILCOR states that initial inflation pressures of 20-25 cm is effective for most preterm infants.

Recommendation: ***Use the same level of fresh gas flow, CPAP and PPV for both systems.***

Initial settings: ***Fresh gas flow at 10 l/min*** *(8-15 l/min allowed). Humidification allowed if used for both systems.* ***CPAP initially 5 cm H2O*** *(4-8 cm H2O allowed) and* ***PPV 20 cm H2O*** *(18-25 cm H2O allowed).*

Adjust CPAP and PPV as needed.

Instructions on usage of resuscitation systems

T-piece: Use a face mask that fits over the mouth and nose of the patient. Hold the mask tight to the patient face to minimize leakage.

New system: Use a nasal prong size that fits tightly into the nostrils of the patient. Hold the system in a position that minimizes leakage. The mouth should be closed gently with a finger and held closed throughout the stabilisation period.

Both systems: The head should be held in the correct anatomical position to secure a free airway. When giving positive pressure ventilation the outlet is occluded with a finger. Give 60-90 breaths per minute.

Failed ventilation strategies and change of resuscitation systems (crossover not allowed)

Background: Ensuring adequate ventilation is a key component of resuscitation and stabilisation. A back-up plan for failed ventilation is needed if ventilation is inadequate. Rescue should be available with an alternative system if needed.

Recommendation:

Follow the hospital standard for failed ventilation. ***Cross-over between the two systems is not allowed.***

- *Evaluate airway and PPV level*
- *Rescue for* ***T-piece system*** *is bag and mask ventilation*
- *Rescue for the* ***new system*** *is 1) change from prongs to face mask interface or 2) bag and mask ventilation*
- *Always consider intubation*

Report rescue in forms. If problems with equipment consider immediate alert to principal investigator or coordinator. Report cross-over as protocol violation.

Sustained inflation

Background: The 2015 ILCOR guidelines suggest against the routine use of initial SI (greater than 5 seconds duration) for preterm infants without spontaneous respirations immediately after birth because of lack of evidence fore effectiveness and safety. In a new review of the literature there is concern about a trend toward more airleak and a higher rate of intraventricular haemorrhage that is worrisome without clear long term benefits.[11]

Recommendation: Sustained inflation is not recommended. Report as protocol violation

Delivery Room Intubation (primary outcome)

Background: To provide strict criteria for delivery room (DR) intubation is difficult. The ILCOR guidelines gives no detailed criteria. The clinical reasons for intubation that need to be considered are, apnea, bradycardia, severe respiratory distress. This has to be evaluated after adequate PPV, CPAP and related to time after birth. Oxygen demand and SpO2 also has to be reviewed.

The trial recommendations are similar to previous studies using delivery room intubation criteria as outcome.

Recommendation

Criteria for intubation:

No or inadequate response to PPV and CPAP. Defined by one of the following:

1. *bradycardia HR<100 despite 60 seconds of effective PPV*
2. *apnea*
3. *poor respiratory effort during the intervention*
4. *inadequate oxygenation and respiratory distress*

Surfactant after intubation in DR

Background: All infants that are intubated in delivery room should receive surfactant.[4 12]

Recommendation: After delivery room intubation an intra-tracheal installation of surfactant should be given. Type of surfactant and dosage is not specified.

Switch to NCPAP after initial stabilisation of spontaneous breathing infant.

Background: After initial stabilisation (at least ten minutes) a spontaneous breathing infant continues with NCPAP respiratory support.

*Recommendation: Continue randomised system treatment for **at least 10 minutes** and the infant has stable breathing before changing to standard NCPAP. The NCPAP system is not specified. The NCPAP system used should be according to local tradition as well as CPAP level and interface. High flow cannulae and NIPPV is not recommended but can be used according to local tradition or guidelines.*

Intubation and surfactant after initial stabilisation

The following sections apply after the intervention has finished and the infant is spontaneously breathing on non-invasive respiratory support or has been intubated.

Non-invasive respiratory support

Background: Mechanical ventilation may be lifesaving but can cause lung injury. When possible mechanical ventilation should therefor be avoided and respiratory support given with non-invasive respiratory support such as NCPAP.[4 6]

Non-invasive respiratory support can be defined as any form of respiratory support that is not delivered via an endotracheal tube. It includes NCPAP, nasal intermittent positive pressure ventilation (NIPPV) and humidified oxygen delivered by high-flow nasal cannulae.[13 14]

Recommendation:

- When possible maintain infants on NCPAP. This is preferred over mechanical ventilation.The interface should be short binasal prongs or mask and a starting pressure of at least 5 cm H_2O should be applied. CPAP level can then be individualized depending on clinical condition, oxygenation and perfusion.

- A trial of NIPPV can be considered to reduce the risk of intubation in infants failing on CPAP; however, this may not offer any significant long-term advantages.[13]
- Methylxanthines therapy should be used to minimize risk for apnea
- High-flow nasal cannulae is not recommended because of lack of evidence of efficacy and safety from high-quality randomized controlled trials in ELBW infants.[4]

Intubation criteria <72 h

The following recommendation presents “minimal criteria” for intubation after initial stabilisation. The purpose is to avoid unnecessary intubation of study patients. Providing strict criteria for failure on NCPAP could minimize the risk of bias in this un-blinded trial but are difficult to provide. The decision to intubate and mechanically ventilate a patient also has to consider given or planned surfactant treatment. We recognise that individual units may have specific guidelines that do not agree on all these points

Background: NICU intubation criteria have been extensively reviewed in the NIPPV Study protocol Appendix 5.[15] In prior RCTS including trials of NIPPV versus CPAP and comparing CPAP to mechanical ventilation, the investigators highlighted the importance of 3 components: a) repeated apnea or desaturation, b) increasing oxygen requirements and c) hypercarbia with acidosis

Treatment should aim at early rescue for developing RDS.[4]

Recommendation*:* One or more of the following criteria must be present for intubation:

1. Apnea: more than 1 MAJOR episode of apnea (requiring PPV) in a 6 hour period OR ≥6 MINOR episodes (requiring moderate stimulation) in 6-hour period. Caffeine should be given prior to decision to intubate on the apnea indication. Do NOT consider those spells of apnea that occur during: a) trials of nasal prongs b) feeding c) suctioning or handling

2. Clinical and radiological signs of RDS

3. pH<7.22 and $PaCO_2$ >9.5 kPa on consecutive arterial or capillary measurements;

4. need for general anaesthesia, surgery or logistics

Surfactant

Background: If surfactant treatment is needed, the earliest possible administration is recommended, but this comes with the caveat that there is no

consistently reliable predictive test to determine whether an individual baby is at risk of developing severe RDS.

RDS definition/Need for surfactant criteria:

1) Clinical signs of respiratory distress including cyanosis, grunting, retractions and tachypnea

2) Chest X-ray with a classical 'ground glass' appearance and air bronchograms.

3) FiO2 >30% in infants <26w and >40% in infants >26w

Mechanical ventilation can be avoided by using the 'INSURE' (INtubate – SURfactant – Extubate to CPAP) technique and this method has been shown in randomized trials to reduce the need for mechanical ventilation and subsequent bronchopulmonary dysplasia (BPD). The earlier the decision is made to use the INSURE technique, the greater the chance of avoiding ventilation, although more surfactant will be used. More recently techniques have been developed to deliver surfactant intratracheally whilst avoiding traditional intubation by using a fine catheter with the baby spontaneously breathing on CPAP, and these methods have shown promise in terms of achieving a clinical response without passing an endotracheal tube or using PPV although no improved effects on long-term outcome have so far been demonstrated.

Following surfactant administration there may, after a variable period of time, be a need for a further dose of surfactant. It is practical to use a flexible dosing schedule basing the time of repeat doses on the baby's clinical condition and oxygen requirements and there are pharmacokinetic data to support this approach.[4]

Recommendation: Treatment should aim at early rescue for developing RDS wich is defined as increasing oxygen demand, typical x-ray and respiratory distress. FiO_2 > 0.30 for <26w gestational age and FiO2 >0.40 for ≥26w gestational age.

Methylxanthines (caffeine, theophylline, aminophylline)

Background: Methylxanthines is recommended to infants <1250 in the European concensus guidelines based on the CAP study (Grade B). It is also recommended for apnea of prematurity (Grade A).[4]

Recommendation: Methylxanthines should be given as soon as possible to infants in non invasive ventillation. Substance and dosage should follow local routine. Report

Mechanical ventilation

If mechanical ventilation (MV) is needed ventilation strategies should aim at minimising trauma to the lung. There is no concensus which ventilation strategy is best and these differs

a lot between centres and countries. A Cochrane review in 2010 concluded that volume-targeted ventilation reduces significantly the duration of MV when compared with pressure-limited ventilation.[16] Duration of MV and type of MV is not a secondary outcome and will not be recorded.

Recommendations: mechanical ventilation strategies should aim at minimising trauma to the lung. Type of ventilation is not specified and is not reported. Report use of mechanical ventilation within 72 hours.

Weaning and Extubation

This protocol will not define strict weaning criteria, but it is to be understood that reasonable attempts should be made to extubate these infants. While it is understood that some centres may be using somewhat more severe FiO2 and PaCO2 criteria than those listed here, these Criteria are in line with criteria used in other similar studies.

As stated in a review from 2002: “there is not consensus about the most appropriate way to wean babies from mechanical ventilation and their management remains largely subjective depending on institutional or individual practices or preferences”. [17]

We suggest the following citeria as a guide to extubation. These consensual recommendations were compiled from various sources including previous RCTs, local treatment guidelines and clinical experience.

Recommended extubation criteria:

- Targets for gas exchange during ventilation should aim to minimize on-going baro/volutrauma and hyper-oxygenation: $PaCO_2$ 5,5-8 kPA and pH > 7.22 (arterial or capillary samples).
- An FiO2 = <0.35 with a SaO2 = >90% .
- A mean airway pressure (MAP) <10 cm H_2O, ventilator rate < 20 bpm, an amplitude < 2X MAP if on high frequency ventilation (HFO).
- No attempt should be made to wean from low rate intermittent mandatory ventilation, or synchronised IMV via a period of ETT CPAP. This approach has been shown in a neonatal RCT to increase the work of breathing, leading to higher failure rate.[18]
- Hemodynamically stable (Acceptable blood pressure and perfusion in the opinion of the clinical team – such an infant may be receiving inotropic / vasopressor agents, but should not require on-going volume infusions to stabilize the circulation or increase in any continuously infused medications for circulatory stabilization the last hour prior to extubation).
- Absence of clinically significant PDA (Defined as echo confirmation of L-R shunting with increased LA/Ao size)

Amendments

Version 1.1 Logistics added as criteria for NICU intubation (number 5). No review needed.

Version 1.2 Drafts of changes, not released.

Version 1.3 Updated ILCOR 2015 publication. Language review. Discussion of FIO2 criteria for post delivery room intubations. No review needed.

Version 1.4 Paragraph with instructions on usage of T-piece and new system added. No review needed.

Version 1.5 Recommendation on use of humidification during resuscitation added in section “Temperature maintenance” and “PPV and CPAP for the two resuscitation systems”.

Version 1.6 CORSAD28 changed to CORSAD

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eAppendix 2. Data management committee instructions

A RANDOMISED CONTROLLED TRIAL OF DELIVERY ROOM INTUBATION RATES COMPARING A NEW SYSTEM AND T-PIECE RESUSCITATION SYSTEM FOR INITIAL STABILISATION OF INFANTS BORN <28 WEEKS

Appendix to Clinical Investigation Plan

Clinical investigation of medical devices for human subjects: Good clinical practice (ISO 14155:2011)

Composition

***Mikael Norman**, Professor in Pediatrics, Senior Consultant Neonatology*
Karolinska Institutet, Stockholm (Chairman)

***Stellan Håkansson**, Associate Professor, Senior Consultant Neonatology*
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Roles and responsibilities

The Data Monitoring Committee (DMC) is an independent group of experts that advises the study Principal Investigator. The primary responsibilities of the DMC are to 1) periodically review and evaluate the accumulated study data for participant safety, study conduct and progress, and, when appropriate, efficacy, and 2) make recommendations to study investigators concerning the continuation, modification, or termination of the trial. The DMC considers study-specific data as well as relevant background knowledge about the patient population under study.

The DMC should review each protocol for any major concern prior to implementation. During the trial, the DMC should review cumulative study data to evaluate safety, study conduct, and scientific validity and integrity of the trial. As part of this responsibility, DMC members must be satisfied that the timeliness, completeness, and accuracy of the data submitted to them for review are sufficient for evaluation of the safety and welfare of study participants. The DMC should also assess the performance of overall study operations and any other relevant issues, as necessary.

Items reviewed by the DMC include:

- Interim/cumulative data for evidence of study-related adverse events;
- Interim/cumulative data for evidence of efficacy according to pre-established statistical guidelines, if appropriate;
- Data quality, completeness, and timeliness;
- Performance of individual centers;

- Adequacy of compliance with goals for recruitment and retention;
- Adherence to the protocol;
- Factors that might affect the study outcome or compromise the confidentiality of the trial data (such as protocol violations, unmasking, etc.); and,
- Factors external to the study such as scientific or therapeutic developments that may impact participant safety or the ethics of the study.

The DMC should conclude each review with their recommendations to the study Principal Investigator as to whether the study should continue without change, be modified, or terminated. Recommendations regarding modification of the design and conduct of the study could include:

- Modifications of the study protocol based upon the review of the safety data;
- Suspension or early termination of the study or of one or more study arms because of serious concerns about subjects' safety, inadequate performance or rate of enrollment;
- Suspension or early termination of the study or of one or more study arms because study objectives have been obtained according to pre-established statistical guidelines;
- Optional approaches for investigators to consider when the DMC determines that the incidence of primary study outcomes is substantially less than expected such as recommendations to increase the number of trial centers or extend the recruitment period; and,
- Corrective actions regarding a study center whose performance appears unsatisfactory or suspicious.
- Confidentiality must always be maintained during all phases of DMC review and deliberations. Usually, only voting members of the DMC should have access to interim analyses of outcome data by treatment group. Exceptions may be made when the DMC deems it appropriate. The reason and to whom the exceptions for access to interim analyses is granted will be documented in the Closed Session Report. DMC members must maintain strict confidentiality concerning all privileged trial results ever provided to them. The DMC should review data only by masked study group (such as X vs. Y rather than experimental vs. control) unless or until the DMC determines that the identities of the groups are necessary for their decision-making. If more detail is needed the Principal Investigator will provide access to patient records. Whenever masked data are presented to the DMC, the key to the group coding must be available for immediate unmasking.

Conflict of Interest

No member of the DMC should have direct involvement in the conduct of the study. Furthermore, no member should have financial, proprietary, professional, or other interests

that may affect impartial, independent decision-making by the DMC. Communication on any outcome variable to persons outside the DMC is not accepted

Meetings

The frequency of DMC meetings depends on several factors including the rate of enrollment, safety issues or unanticipated adverse events, availability of data, and, where relevant, scheduled interim analyses.

The initial DMC meeting should occur before the start of the trial. At this meeting the DMC should discuss the protocol and the DMC charter, including triggers set for data review or analyses, definition of a quorum, and guidelines for monitoring the study. Guidelines should also address stopping the study for safety concerns and, where relevant, for efficacy based on plans specified in the protocol. At this meeting, the DMC should also develop procedures for conducting business (e.g., voting rules, attendance, etc.). At this meeting the Coordinating Investigator and trial statistician will be available for consultation.

Once a study is implemented, the DMC should convene as often as necessary, but at least once annually, to examine the accumulated safety and enrolment data, review study progress, and discuss other factors (internal or external to the study) that might impact continuation of the study as designed. A DMC meeting may be requested by DMC members or study Coordinating Investigator at any time to discuss safety concerns.

Previous versions

1.0 EPN	Version used for EPN
1.1	Names of members included

eAppendix 3. Summary of stillborn, infants not receiving allocated treatment, deaths, and miscellaneous

Stillborn infants excluded after randomization

Four stillborn was not included in the analysis as intention to treat (n=3 new system and n=1 T-piece). None of these had CPR performed and all were <24 weeks GA. One case reported as stillborn also had immediate treatment limitations. This infant had APGAR 0-0-0, a myelomeningocele, was not breathing and resuscitation was not started.

Deaths in Delivery Room (DR).

A total of four infants died in DR (n=3 new system and n=1 T-piece). All cases were reviewed by the Data Monitoring Committee (DMC) and none of the cases could be connected to the study intervention or the randomized system. Below is a description of the cases.

New device (n=3):

Born in w 24 GA. Preeclampsia. APGAR 2-2-2. Intubation at 3 minutes of age, surfactant followed by CPR and adrenaline, fluids, buffers and transfusion. The infant did not respond and died in the delivery room after 61 minutes of resuscitation.

Born in w 23 GA. Placenta ablatio, hypovolemic. APGAR 1-1-1. Intubated and surfactant but no response. Treatment limitation because of low GA and poor prognosis. Infant died in DR at 22 min of age.

Born in w 23 GA. PROM in w 21 GA. APGAR 1-1-1. BW under 500g and very immature. Did not receive any interventions after decision on treatment limitations at 3 minutes of age. Comfort care. Death confirmed when infant auscultated at 66 min of age.

T-piece (n=1):

Born in w 23 GA. Ruptured membranes in w 20 GA. Born in w 23, chorioamnionitis. APGAR 2-5-2. Intubated at 3 minutes of age. Surfactant x 3. No improvement with high inflation pressures and very low tidal volumes. Judged as lung hypoplasia, treatment limitations and infant dies in DR at 21 min of age.

Deaths in NICU

A total of 12 infants died in NICU (n=6 new system and n=6 T-piece group). All cases were reviewed by the Data Monitoring Committee (DMC) and none of the cases could to be connected to the study intervention or the randomized system.

Infants that did not receive allocated treatment

A total of 7 patients did not receive allocated treatment, (n=5 new system and n=2 T-piece).

Additional patients with miscellaneous problems and AE that were classified as minor problems of adherence but not as ‘not receiving allocated treatment’ are available at the end of the supplement.

New system group

1. T-piece was used by mistake (no new system packed in resuscitation bag). *Intubated at 8 minutes of age. At 72 hours follow-up the infant was still on a ventilator. No complications noted.*
2. The team arrived too late (emergency c-section) and the anesthesiologist had already started ventilation with T-piece. *The infant was not intubated in DR. At 2 hours the infant was intubated for mechanical ventilation in the NICU.*
3. There was no oxygen blender available to drive new system and T-piece was used. *Infant was not intubated and never received mechanical ventilation.*
4. SIB was used because of an unrecognized humidifier tubing connector leakage. *The infant was never intubated and never received mechanical ventilation.*
5. There was no investigator available and T-piece was used. *The infant was intubated at 10 minutes of age. The infant died at 57 with IVH and lung bleed noted in records.*

T-piece

1. In one case the new system was used by mistake. An unknown user error resulted in problems with increasing PIP. Malfunction or problems could not be confirmed when testing the equipment and there were no similar reports to the manufacturer. *The infant was intubated at 3 minutes of age due to inadequate breathing. At 72 hours follow-up the patient was extubated and had no complications.*
2. SIB was used because of humidifier was disconnected and T-piece could not deliver pressure. First ventilated with bag and mask before resuming T-piece ventilation. *Intubated at 7 min of age due to inadequate breathing. At 72 hours the infant was intubated and IVH grade I-II and early septicemia was noted in the records.*

Change from prongs to face mask for new system

The interface was changed from nasal prongs to face mask in 9 patients treated with the new system as rescue and according to protocol.

Miscellaneous on protocol adherence problems and registered adverse events

There were some problems with protocol adherence related to user errors and mistakes. These were judged by DMC as not related to the study protocol and the most common action was to inform investigators and highlight the management protocol.

For the new system:

1. One infant was reported as being difficult to ventilate with prongs and T-piece was used before intubation at 6 minutes of age. *SIB or face mask should have been used.*
2. One infant had multiple interventions including CPR and adrenaline. At 12 minutes the system was changed to T-piece. The infant did not improve and was intubated at 27 minutes of age. *SIB or face mask should have been used.*
3. One birth of twins had problems with adjusting CPAP above 4 cm H2O for the new system when used with a resuscitation table driver. Investigated by PI and problem related to wall gas supply. No rescue system used, no cross-over. Both twins were intubated before 10 minutes of age. *AE related to gas supply and addressed.*
4. One infant was noted as having oedema on bridge of nose. The infant was intubated at 8 minutes. No other problems noted, at 72 hours the infant was on NIPPV. *Contact with treating clinicians who stated this was minor and did not cause problems.*
5. In one infant the resuscitation table was first positioned so that tubing was not sufficiently long. T-piece initially used before this was fixed. The infant was never intubated and no problems recorded apart from an IVH I-II. *SIB should have been used.*
6. For one birth gas supply was not turned on. This resulted in a switch from prongs to face mask for the new system before identification of the problem at <1 minute. *SIB should have been used.*
7. One infant did not receive full 10 minutes on new system. *Minor deviation from protocol.*

For T-piece:

One infant did not receive full 10 minutes on T-piece. *Minor deviation from protocol.*

One case of problem with incubator temperature was not included.