



Full title: The efficacy and safety of two topical antiseptic solutions for skin disinfection prior to percutaneous central venous catheter insertion in preterm neonates: a feasibility study

Chief Investigator: Dr Paul Clarke

EudraCT: 2015-000874-36

ISRCTN: 82571474

Final Analysis

Version 0.11

Data snapshot date: 15 October 2019

Analysis date: 21 January 2020

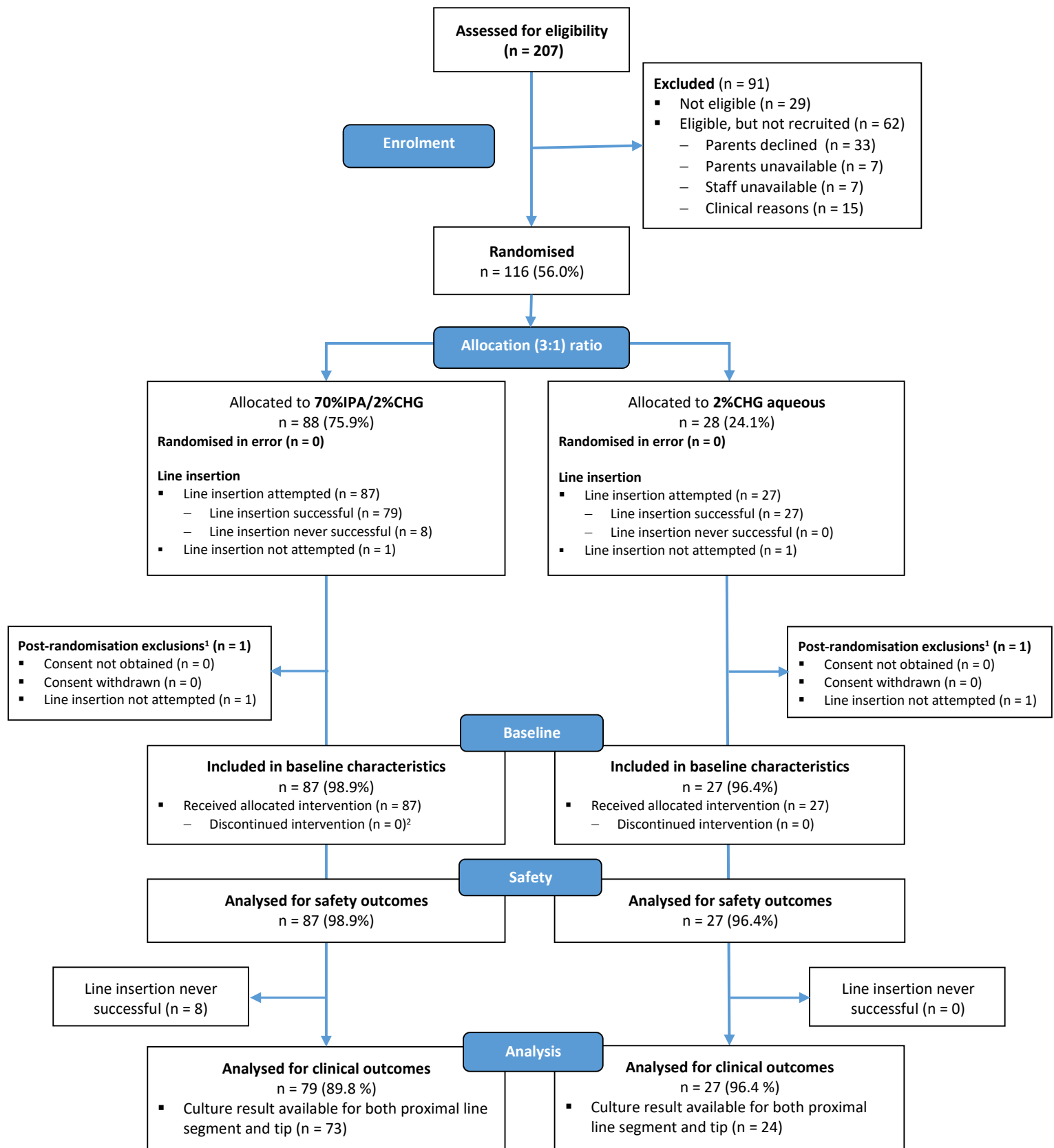
Authors: Jennifer Bell (Medical statistician, NPEU CTU)
Christopher Partlett (previous medical statistician, NPEU CTU)

Reviewers: Louise Linsell (Senior medical statistician, NPEU CTU)
Paul Clarke (Chief investigator, Norwich and Norfolk University Hospital, NICU)

Table of Contents

| | |
|---|-----------|
| Figure 1: Flow of participants | 3 |
| Table 1A: Infant characteristics at trial entry | 4 |
| Table 1B: Maternal characteristics at trial entry | 5 |
| Table 2: Primary outcome | 6 |
| Table 3A: Feasibility metrics | 7 |
| Table 3B: Completeness of data | 7 |
| Table 4A: Bacterial species (microbiology lab culture result) | 8 |
| Table 4B: Bacterial species typed via molecular methods (for relevant paired isolates) | 11 |
| Table 5: Secondary outcomes: bacteriology and sepsis | 12 |
| Table 6: Process outcomes and adherence | 13 |
| Table 7: Safety outcomes | 14 |
| Table 8: Supplementary information | 15 |
| Document history | 16 |

Figure 1: Flow of participants



¹Not mutually exclusive.

²A discontinuation form was completed in error for infant 10156 who was transferred to another hospital with line in situ following application of the randomised allocation. This infant has therefore not been reported as a discontinuation. More information is in K:\NPEUDATA\Current trials\ARCTIC\Statistics - Restricted\Analysis\Final\2019-10-15\Data Queries\Incident - 10156

Table 1A: Infant characteristics at trial entry

(Minimisation factors highlighted)

| | 70%IPA/2%CHG (n = 87) | 2%CHG aqueous (n = 27) |
|---|--------------------------|---------------------------|
| Centre, n (%) | | |
| Norfolk | 56 (64.4) | 17 (63.0) |
| Medway | 31 (35.6) | 10 (37.0) |
| Missing | 0 | 0 |
| Male sex, n (%) | 46 (52.9) | 13 (48.1) |
| Missing | 0 | 0 |
| Infant's birthweight (g) | | |
| Mean (SD) | 1089.0 (340.5) | 1074.5 (366.3) |
| Range | (508 to 2150) | (575 to 1900) |
| <500g | 0 | 0 |
| 500 to 999g | 39 (44.8) | 15 (55.6) |
| 1000 to 1499g | 37 (42.5) | 8 (29.6) |
| >1500g | 11 (12.6) | 4 (14.8) |
| Missing | 0 | 0 |
| Gestational age (completed weeks) ¹ | | |
| Median (IQR) | 28 (26 to 30) | 28 (26 to 30) |
| Range | (23 to 32) | (23 to 33) |
| <26 ⁺⁰ | 20 (23.0) | 5 (18.5) |
| 26 ⁺¹ to 27 ⁺⁶ | 19 (21.8) | 7 (25.9) |
| 28 ⁺⁰ to 33 ⁺⁶ | 48 (55.2) | 15 (55.6) |
| Missing | 0 | 0 |
| One of a multiple pregnancy, n (%) | 16 (18.4) | 9 (33.3) |
| Missing | 0 | 0 |
| Mode of delivery, n (%) | | |
| Vaginal | 29 (33.3) | 7 (25.9) |
| Caesarean | 58 (66.7) | 20 (74.1) |
| Missing | 0 | 0 |
| Membranes ruptured prior to labour, n (%) | 35 (41.7) | 9 (36.0) |
| > 24 hours before delivery | 20 (57.1) | 6 (66.7) |
| ≤ 24 hours before delivery | 15 (42.9) | 3 (33.3) |
| Unknown | 0 | 0 |
| Missing | 3 | 2 |
| Apgar score at 5 minutes | | |
| Median (IQR) | 8 (7 to 9) | 8 (6 to 9) |
| < 4 | 2 (2.4) | 2 (7.7) |
| Missing | 2 | 1 |
| First recorded temperature on admission to the neonatal unit after birth, mean (SD) | 36.8 (0.7) | 36.8 (0.9) |
| Missing | 0 | 0 |
| Infant ventilated via an endotracheal tube at the time of randomisation, n (%) | 34 (39.1) | 13 (50.0) |
| Missing | 0 | 1 |
| Infant born in recruiting hospital, n (%) | 68 (78.2) | 19 (70.4) |
| Missing | 0 | 0 |
| Any surgical procedure prior to randomisation, n (%) | 6 (6.9) | 1 (3.7) |
| Missing | 0 | 0 |

| | 70%IPA/2%CHG (n = 87) | 2%CHG aqueous (n = 27) |
|--|----------------------------------|-----------------------------------|
| Prophylactic antifungal medication at the time of randomisation, n (%) | 27 (31.0) | 9 (33.3) |
| Missing | 0 | 0 |
| Infant received antibiotics prior to randomisation, n (%) | 78 (98.7) | 26 (96.3) |
| Missing | 8 | 0 |
| Devices in situ at time of PCVC insertion, n (%) | | |
| Chest drain | 1 (1.3) | 0 (0.0) |
| Endotracheal tube | 28 (35.4) | 12 (44.4) |
| Peripheral arterial line | 2 (2.5) | 2 (7.4) |
| Peripheral venous cannula | 70 (88.6) | 18 (66.7) |
| UAC (umbilical arterial catheter) | 24 (30.4) | 11 (40.7) |
| UVC (umbilical venous catheter) | 43 (54.4) | 14 (51.9) |
| Other | 2 (2.5) | 0 (0.0) |
| Missing | 8 | 0 |

Table 1B: Maternal characteristics at trial entry

| | 70%IPA/2%CHG (n = 87) | 2%CHG aqueous (n = 27) |
|--|----------------------------------|-----------------------------------|
| Mother's age (years), mean (SD) | 29.7 (6.0) | 29.4 (5.7) |
| Missing | 0 | 0 |
| Any antenatal corticosteroids, n (%) | 80 (92.0) | 24 (88.9) |
| Missing | 0 | 0 |
| Received antibiotics within the week before delivery, n (%) | 27 (31.0) | 8 (29.6) |
| Missing | 0 | 0 |
| Pyrexial in labour (temperature > 38.0 °C), n (%) | 4 (4.8) | 0 (0.0) |
| Missing | 3 | 0 |
| Chorioamnionitis suspected clinically before delivery, n (%) | 7 (8.0) | 1 (3.7) |
| Missing | 0 | 0 |

Table 2: Primary outcome

Proportion of babies with catheter colonisation as determined by positive bacterial culture (significant growth) from one or both of the catheter segments taken at catheter removal. The primary outcome is the proportion in the 70%IPA/2%CHG arm.

| | 70%IPA/2%CHG (n = 79) |
|---|----------------------------------|
| Catheter colonisation as determined by positive bacterial culture from at least one of the two catheter segments taken at catheter removal, n (%) | 3 (4.1) |
| Positive tip alone | 1 |
| Positive proximal segment alone | 2 |
| Both tip and proximal segment positive | 0 |
| Missing | 6 |
| Proportion of babies with catheter colonisation (95% confidence interval) | 4.1 (0.9, 11.5) |

Table 3A: Feasibility metrics

Rates of recruitment and retention to the study.

| | Total eligible¹ (n = 178) |
|--|---|
| Uptake rate | |
| Number of eligible infants randomised, n (%) | 116 (65.2) |
| Proportion (95% CI) | 65.2 (57.7, 72.1) |

| | 70%IPA/2%CHG (n = 88) | 2%CHG aqueous (n = 28) | All (n = 116) |
|--|----------------------------------|-----------------------------------|--------------------------|
| Retention² | | | |
| Number of infants who remained in the study, n (%) | 73 (83.0) | 24 (85.7) | 97 (83.6) |
| Proportion (95% CI) | 83.0 (73.4, 90.1) | 85.7 (67.3, 96.0) | 85.1 (77.2, 91.1) |

¹Eligible infants are defined as those who were recruited or not recruited (including those who declined to participate) but who were clinically eligible.

²Proportion of infants that remained in the study to provide complete primary outcome and safety data

Table 3B: Completeness of data

| | Total³ (n = 106) |
|--|--|
| Infants with no missing data collection forms, n (%) | 104 (98.1) |
| Overall form completeness for required forms, n (%) | |
| Form 1: Trial Entry and Randomisation Form | 106 (100.0) |
| Form 2: Main Outcome Data Form | 106 (100.0) |
| Form 4: PCVC Removal Form | 104 (98.1) ⁴ |
| Form 5: Microbiology Data Form | 106 (100.0) |
| Form 8: End of Study | 106 (100.0) |

³Analysed for clinical outcomes – infants who had a successfully inserted catheter and received the intervention

⁴Two participants did not complete the study as they were transferred, and so PCVC Removal Forms were not required.

Table 4A: Bacterial species (microbiology lab culture result)

Bacterial species (microbiology lab culture result) identified on positive blood culture, exit site skin swab (before and after disinfection), and catheter segments (proximal and tip) for infants with at least one positive lab culture result. Coagulase negative staphylococcus species is provided for cases where species was reported.

| Study no. | Allocation | Blood cultures | | | | | Exit site skin swab | | Catheter segment | |
|-----------|--------------|----------------|--------------------------------|------------------------------------|--------------------------|-----|---------------------------------------|--------------------------|--------------------------|-----------|
| | | Sample taken? | Closest to PCVC removal (days) | Blood culture results | | | Before disinfection | After disinfection | Proximal | Tip |
| 10031 | 70%IPA/2%CHG | Yes | 6.2 pre | No growth | No growth | - | Coag-neg – Staph-capitis | No growth | No growth | No growth |
| 10048 | 70%IPA/2%CHG | No | - | N/A | N/A | N/A | No growth | No growth | Coag-neg - Staph-capitis | No growth |
| 10103 | 70%IPA/2%CHG | Yes | 0.3 pre | Other - Mixed CoNS (not specified) | No growth | - | No growth | No growth | No growth | No growth |
| 10111 | 70%IPA/2%CHG | No | - | N/A | N/A | N/A | Coag-neg – Staph-haemolyticus | No growth | No growth | No growth |
| 10195 | 70%IPA/2%CHG | Yes | 0.0 post | Coag-neg – Staph-epidermidis | Coag-neg – Staph-capitis | - | No growth | No growth | No growth | No growth |
| 10225 | 70%IPA/2%CHG | Yes | 1.8 post | No growth | - | - | Coag-neg – Staph-capitis | No growth | No growth | No growth |
| 10278 | 70%IPA/2%CHG | Yes | 0.9 post | No growth | - | - | No growth | Coag-neg – Staph-capitis | No growth | No growth |
| 10284 | 70%IPA/2%CHG | No | - | N/A | N/A | N/A | Coag-neg Staph-epidermidis | No growth | No growth | No growth |
| 10307 | 70%IPA/2%CHG | No | - | N/A | N/A | N/A | Mixed coag, neg staph (not specified) | No growth | No growth | No growth |
| 10321 | 70%IPA/2%CHG | Yes | 1.3 post | Coag-neg – Staph (not specified) | - | - | No growth | No growth | No growth | No growth |
| 10466 | 70%IPA/2%CHG | Yes | 0.0 post | No growth | Coag-neg – Staph-capitis | - | No growth | No growth | No growth | No growth |

| Study no. | Allocation | Blood cultures | | | | | Exit site skin swab | | Catheter segment | |
|-----------|--------------|----------------|--------------------------------|---|-------------------------------|--------------------------|---|--------------------|--------------------------|--------------------------|
| | | Sample taken? | Closest to PCVC removal (days) | Blood culture results | | | Before disinfection | After disinfection | Proximal | Tip |
| 10539 | 70%IPA/2%CHG | No | - | N/A | N/A | N/A | Coag-neg – Staph-capitis | No growth | No growth | Coag-neg – Staph-capitis |
| 10609 | 70%IPA/2%CHG | Yes | 1.4 post | No growth | Coag-neg – Staph-haemolyticus | - | No growth | No growth | No growth | No growth |
| 10650 | 70%IPA/2%CHG | Yes | 0.0 post | Coag-neg – Staph-haemolyticus & Staph-epidermidis | No growth | - | Coag-neg - staph capitis | No growth | No growth | No growth |
| 10686 | 70%IPA/2%CHG | Yes | 1.7 post | Coag-neg – Staph-capitis | Coag-neg – Staph-capitis | No growth | No growth | No growth | Coag-neg – Staph-capitis | No growth |
| 10789 | 70%IPA/2%CHG | Yes | 6.1 pre | No growth | Coag-neg – Staph-capitis | - | Coag-neg – Staph-capitis | No growth | No growth | No growth |
| 10897 | 70%IPA/2%CHG | Yes | 0.2 pre | Coag-neg – Staph-haemolyticus | No growth | Coag-neg – Staph-capitis | No growth | No growth | No growth | No growth |
| 10917 | 70%IPA/2%CHG | Yes | 5.8 pre | Coag-neg – Staph-haemolyticus | Coag-neg – Staph-epidermidis | No growth | No growth | No growth | No growth | No growth |
| 10955 | 70%IPA/2%CHG | No | - | N/A | N/A | N/A | Coag-neg – Staph-warneri | No growth | No growth | No growth |
| 10963 | 70%IPA/2%CHG | Yes | 0.2 pre | No growth | Coag-neg – Staph-capitis | No growth | No growth | No growth | No growth | No growth |
| 11012 | 70%IPA/2%CHG | No | - | N/A | N/A | N/A | Other – 1. Staph-capitis; 2. Staph-aureus | No growth | No growth | No growth |
| 11064 | 70%IPA/2%CHG | Yes | - | Coag-neg – Not specified | - | - | <i>missing</i> ¹ | <i>missing</i> | <i>missing</i> | No growth |
| 11118 | 70%IPA/2%CHG | No | - | N/A | N/A | N/A | Coag-neg – Staph-haemolyticus | No growth | No growth | No growth |

| Study no. | Allocation | Blood cultures | | | | | Exit site skin swab | | Catheter segment | |
|-----------|---------------|----------------|--------------------------------|--|--------------------------|-----|--|--------------------------|------------------------------|------------------------------|
| | | Sample taken? | Closest to PCVC removal (days) | Blood culture results | | | Before disinfection | After disinfection | Proximal | Tip |
| 10060 | 2%CHG aqueous | Yes | 1.7 post | No growth | - | - | Coag-neg – Staph-haemolyticus | No growth | No growth | No growth |
| 10168 | 2%CHG aqueous | Yes | 0.0 post | Coag-neg – Staph-warneri | No growth | - | No growth | No growth | No growth | No growth |
| 10243 | 2%CHG aqueous | Yes | 0.3 pre | No growth | Coag-neg – Staph-warneri | - | No growth | No growth | No growth | Coag-neg – Staph-warneri |
| 10290 | 2%CHG aqueous | No | - | N/A | N/A | N/A | Coag-neg – Staph-haemolyticus ² | No growth | No growth | No growth |
| 10522 | 2%CHG aqueous | No | - | N/A | N/A | N/A | Coag-neg – Staph-capitis | Coag-neg – Staph-capitis | No growth | No growth |
| 10662 | 2%CHG aqueous | Yes | 4.0 pre | Coag-neg – Staph-capitis | No growth | - | No growth | No growth | No growth | No growth |
| 10944 | 2%CHG aqueous | Yes | 0.5 post | Coag-neg – 1. Staph-epidermidis; 2. Staph-capitis. | No growth | - | No growth | missing ³ | No growth | No growth |
| 10981 | 2%CHG aqueous | No | - | N/A | N/A | N/A | Coag-neg – Staph-epidermidis | No growth | Coag-neg – Staph-epidermidis | Coag-neg – Staph-epidermidis |

Coag-neg – Coagulase-negative staphylococcus

Staph-aureus – Staphylococcus aureus

Staph-capitis – Staphylococcal capitis

Staph-epidermis – Staphylococcus epidermis

Staph-haemolyticus – Staphylococcus haemolyticus

Staph-warneri – Staphylococcus warneri

Mixed CoNS – Mixed coagulase-negative staphylococci

¹ Infant was transferred to a non-participating site where their line was removed

² Detail of species was not captured in database, but was found post-data lock. More information is in K:\NPEUDATA\Current trials\ARCTIC\Statistics - Restricted\Analysis\Final\2019-10-15\Data Queries\Incident - 10290

³ Sample not obtained

N/A – not applicable because no blood cultures taken between catheter insertion and 48 hours post removal

Table 4B: Bacterial species typed via molecular methods (for relevant paired isolates)

| Study no. | Allocation | Blood cultures | | | | | Exit site skin swab | | Catheter segment | |
|--|---------------|----------------|--------------------------------|------------------------------|-----------------------------|-----|------------------------------|--------------------|--------------------------|--------------------------|
| | | Sample taken? | Closest to PCVC removal (days) | Blood culture results | | | Before disinfection | After disinfection | Proximal | Tip |
| Catheter-related sepsis cases (n = 2) | | | | | | | | | | |
| 10243 | 2%CHG aqueous | Yes | 0.3 pre | - | Coag-neg – Staph-warneri | - | N/A | N/A | N/A | Coag-neg – Staph-warneri |
| 10686 | 70%IPA/2%CHG | Yes | 1.7 post | <i>Isolate not retained</i> | Coag-neg – Staph-capitis | N/A | N/A | N/A | Coag-neg – Staph-capitis | N/A |
| Catheter-associated sepsis cases with positive exit site skin swab (n = 2) | | | | | | | | | | |
| 10650 | 70%IPA/2%CHG | Yes | 0.0 post | <i>Isolates not retained</i> | N/A | - | Other – Pantoea ananatis | N/A | N/A | N/A |
| 10789 | 70%IPA/2%CHG | Yes | 6.1 pre | N/A | <i>Isolate not retained</i> | - | Coag-neg – Staph-epidermidis | N/A | N/A | N/A |

Coag-neg – Coagulase-negative staphylococcus

Staph-aureus – Staphylococcus aureus

Staph-capitis – Staphylococcal capitis

Staph-epidermis – Staphylococcus epidermis

Staph-haemolyticus – Staphylococcus haemolyticus

Staph-warneri – Staphylococcus warneri

N/A – not applicable because no relevant isolate to sequence

Table 5: Secondary outcomes: bacteriology and sepsis

| | 70%IPA/2%CHG (n = 79) | 2%CHG aqueous (n = 27) | All (n = 106) |
|--|----------------------------------|-----------------------------------|--------------------------|
| Positive exit-site skin swab at catheter removal (before disinfection), n (%) | 11 (15.1) | 4 (16.7) | 15 (15.5) |
| Missing | 6 | 3 | 9 |
| Positive exit site skin swab at catheter removal (after disinfection), n (%) | 1 (1.4) | 1 (4.3) | 2 (2.1) |
| Missing | 7 | 4 | 11 |
| Culture positive catheter segments at removal, n (%) | 3 (4.1) | 2 (8.3) | 5 (5.2) |
| Positive tip alone | 1 (1.3) | 1 (3.7) | 2 (1.9) |
| Positive proximal segment alone | 2 (2.5) | 0 | 2 (1.9) |
| Both tip and proximal segment positive | 0 | 1 (4.2) | 1 (1.0) |
| Missing | 6 | 3 | 9 |
| Definite catheter-related sepsis, n (%) | 1 (1.5) | 1 (4.5) | 2 (2.3) |
| Missing | 13 | 5 | 18 |
| Catheter-associated sepsis, n (%) | 10 (13.7) | 3 (12.5) | 13 (13.4) |
| Missing | 6 | 3 | 9 |
| Total number of PCVC days | 653 | 223 | 876 |
| Definite catheter-related sepsis, n (rate per 1000 PCVC days) | 1 (1.5) | 1 (4.5) | 2 (2.3) |
| Catheter-associated sepsis, n (rate per 1000 PCVC days) | 10 (15.3) | 3 (13.5) | 13 (14.8) |

Table 6: Process outcomes and adherence

| | 70%IPA/2%CHG (n = 87) | 2%CHG aqueous (n = 27) |
|---|----------------------------------|-----------------------------------|
| Number of anatomical sites with at least one failed PCVC insertion | | |
| Median (IQR) | 0 (0 to 1) | 1 (0 to 2) |
| Range | (0 to 7) | (0 to 4) |
| 1 | 18 (20.7) | 6 (22.2) |
| 2 | 10 (11.5) | 6 (22.2) |
| 3 | 1 (1.1) | 0 |
| 4 | 1 (1.1) | 2 (7.4) |
| Adherence to intervention | | |
| Successful catheterisation (N) | 79 | 27 |
| Insertion done observing strict aseptic technique and in accordance with Working Document "Standardised guideline for catheter insertion utilising good catheter insertion and care practices", n (%) | 79 (100.0) | 27 (100.0) |
| Insertion site disinfected with the allocated study antiseptic prior to successful PCVC insertion, n (%) | 79 (100.0) | 27 (100.0) |
| Baseline skin condition is recorded to describe the PCVC insertion site appearance prior to successful PCVC insertion, n (%) | 79 (100.0) | 27 (100.0) |
| Allocated study antiseptic used to clean the skin before PCVC insertion applied sparingly and for 10 to 20 seconds, n (%) | 79 (100.0) | 27 (100.0) |
| Allocated study antiseptic allowed to dry for at least 30 seconds prior to the successful PCVC insertion, n (%) | 79 (100.0) | 27 (100.0) |
| Following skin disinfection preceding the successful PCVC insertion, no other solution was used to wipe off the antiseptic from the skin ¹ , n (%) | 76 (96.2) | 26 (96.3) |
| Exit site disinfected after first skin swab taken but before PCVC removal ² , n (%) | 75 (96.2) | 24 (92.3) |
| Missing | 1 | 1 |

¹ Two infants in the 70%IPA/2%CHG arm and one in the 2%CHG arm who did have another solution had sterile water used.

² Three infants in the 70%IPA/2%CHG arm and one in the 2%CHG arm who didn't have their exit site disinfected at this time had their line removed at a non-participating site. For one infant in the 2%CHG arm who didn't, the allocated solution could not be located.

Table 7: Safety outcomes

Daily skin morbidity scores in the period between catheter insertion and 48 hours post-catheter removal, and in the period between antiseptic application and 48 hours post antiseptic application where catheterisation was unsuccessful.

| Skin morbidity scores | 70%IPA/2%CHG (n = 87) | 2%CHG aqueous (n = 27) |
|---|--------------------------|---------------------------|
| Worst score for skin dryness throughout safety monitoring period | | |
| Median (IQR) | 1 (1 to 1) | 1 (1 to 1) |
| Range | (1 to 2) | (1 to 2) |
| 1 | 80 (92.0) | 26 (96.3) |
| 2 | 7 (8.0) | 1 (3.7) |
| 3 | 0 | 0 |
| Worst score for erythema throughout safety monitoring period | | |
| Median (IQR) | 1 (1 to 1) | 1 (1 to 1) |
| Range | (1 to 2) | (1 to 2) |
| 1 | 72 (82.8) | 22 (81.5) |
| 2 | 15 (17.2) | 5 (18.5) |
| 3 | 0 | 0 |
| Worst score for breakdown/excoriation throughout safety monitoring period | | |
| Median (IQR) | 1 (1 to 1) | 1 (1 to 1) |
| Range | (1 to 2) | (1 to 2) |
| 1 | 82 (94.3) | 25 (92.6) |
| 2 | 5 (5.7) | 2 (7.4) |
| 3 | 0 | 0 |
| Worst score for totals of all three scores throughout safety monitoring period | | |
| Median (IQR) | 3 (3 to 4) | 3 (3 to 4) |
| Range | (3 to 5) | (3 to 5) |
| 3 | 65 (74.7) | 20 (74.1) |
| 4 | 20 (23.0) | 6 (22.2) |
| 5 | 2 (2.3) | 1 (3.7) |
| 6 | 0 | 0 |

Skin scores are graded as follows:

Dryness

- 1 = Normal, no sign of dry skin
- 2 = Dry skin, visible scaling
- 3 = Very dry skin, cracking/fissures

Erythema

- 1 = No evidence of erythema
- 2 = Visible erythema <50% of skin area exposed to antiseptic
- 3 = Visible erythema ≥50% of skin area exposed to antiseptic

Breakdown/excoriation

- 1 = None evident
- 2 = Small localised areas
- 3 = Extensive

Table 8: Supplementary information

| | 70%IPA/2%CHG (n = 79) | 2%CHG aqueous (n = 27) | Overall (n = 106) |
|--|----------------------------------|-----------------------------------|------------------------------|
| Postnatal age (days) at line insertion, median (IQR) | 5.0 (2.0 to 7.0) | 4.0 (2.0 to 8.0) | 5.0 (2.0 to 7.0) |
| Range (min to max) | (0 to 46) | (1 to 19) | (0 to 46) |
| Catheter inserted in ≤ 3 days after birth, n (%) | 31 (39.2) | 11 (40.7) | 42 (39.6) |
| Anatomical site of long line insertion | | | |
| Upper limb (inc. axilla) | 46 (58.2) | 15 (55.6) | 61 (57.5) |
| Lower limb | 32 (40.5) | 11 (40.7) | 43 (40.6) |
| Scalp | 1 (1.3) | 1 (3.7) | 2 (1.9) |
| At least one blood culture sent while line was in situ, n (%) | 25 (33.3) | 8 (32.0) | 33 (33.0) |
| Missing | 4 | 2 | 6 |
| Time (days) to first positive blood culture during line indwell in infants that had bloodstream infection, N | 11 | 4 | 15 |
| Median (IQR) | 7.0 (5.0 to 10.0) | 5.5 (5.0 to 9.5) | 6.0 (5.0 to 10.0) |
| Line removal details completed, N | 78 | 26 | 104 |
| Postnatal age (days) at line removal, median (IQR) | 13.0 (10.0 to 19.0) | 15.0 (11.0 to 21.0) | 14.0 (10.0 to 20.0) |
| Range (min to max) | (3 to 57) | (3 to 29) | (3 to 57) |
| Duration of line indwelling, median (IQR) | 9.0 (6.0 to 12.0) | 9.5 (7.0 to 12.0) | 9.0 (6.0 to 12.0) |
| Range (min to max) | (1 to 32) | (2 to 20) | (1 to 32) |
| Reason for removal, n (%) (non-exclusive) | | | |
| No longer needed | 68 (87.2) | 20 (76.9) | 88 (84.6) |
| Suspected sepsis | 5 (6.4) | 3 (11.5) | 8 (7.7) |
| Confirmed sepsis | 3 (3.8) | 0 (0.0) | 3 (2.9) |
| Damaged | 0 (0.0) | 1 (3.8) | 1 (1.0) |
| Unintended removal | 1 (1.3) | 0 (0.0) | 1 (1.0) |
| Blocked | 2 (2.6) | 1 (3.8) | 3 (2.9) |
| Malposition confirmed by x-ray | 4 (5.1) | 1 (3.8) | 5 (4.8) |
| Other complications | 1 (1.3) | 1 (3.8) | 2 (1.9) |
| Missing | 1 | 1 | 2 |
| Blood culture sent at time of PCVC removal in those with suspected or confirmed sepsis, N | 8 | 3 | 11 |
| n (%) | 5 (62.5) | 3 (100.0) | 8 (72.7) |
| Antibiotics received on day of PCVC removal, n (%) | 15 (19.2) | 6 (23.1) | 21 (20.2) |
| At least one dose prior to removal, n (%) | 11 (78.6) | 4 (66.7) | 15 (75.0) |
| Missing | 1 | 0 | 1 |
| Within 7 days before removal, n (%) | 10 (100.0) | 4 (100.0) | 14 (100.0) |
| Missing | 1 | 0 | 1 |

Document history

| Version | Dates | Edited by | Comments |
|---------|------------|-----------|--|
| 0.1 | 22/10/2019 | JB | First draft of final analysis |
| 0.2 | 25/10/2019 | JB | Second draft following manual checks |
| 0.3 | 6/11/2019 | JB | Revised figure 1, and other minor changes, following review by LL |
| 0.4 | 7/11/2019 | JB | Further revisions to figure 1 |
| 0.5 | 3/1/2020 | JB | Further revisions and additional supplementary information following review and request by PC |
| 0.6 | 8/1/2020 | JB | Additional details on species and timing of blood culture samples in tables 4a and 4. |
| 0.7 | 9/1/2020 | JB | Edits to figure 1 (removing incorrectly entered discontinuation), tables 4a and 4b (additional detail), and change to title of table 5. |
| 0.8 | 10/1/2020 | JB | Footnote added explaining additional data on infant 10290 in table 4a. Clarification to second footnote on table 6. |
| 0.9 | 20/1/2020 | JB | Minor changes following joint TSC/DMC meeting: Blood cultures in tables 4a & 4b in chronological order, overall total column added to table 5, ranges added to tables 1a and 8, rows with zero missings removed, typos corrected. |
| 0.10 | 21/1/2020 | JB | Added Catheter inserted in ≤ 3 days after birth to table 8 |
| 0.11 | 28/1/2020 | JB | Added details of incidents in footnotes (figure 1, table 4a) |