

Appendix 2

Study within a trial methods

Study/trial registration details

This SWAT was registered in Queens University Belfast SWAT store as SWAT 134.

Study within a trial setting and design

The Oxy-PICU SWAT was a two-arm, cluster RCT, conducted in 15 paediatric critical care units participating in the Oxy-PICU trial. Participating sites were randomised 1 : 1, at a cluster level, to receive site initiation training plus an enhanced education and training package (enhanced training – intervention) or site initiation training and materials alone (no enhanced training – control). Randomisation was conducted by an independent statistician and performed separately for each trial site prior to site opening. Due to the nature of the intervention, it was not possible to blind participants (i.e. research staff at participating sites).

Study within a trial data collection

Data collection for the SWAT was nested within the Oxy-PICU trial data collection. Data on protocol adherence for the two trial interventions and separation between the trial groups within the main Oxy-PICU trial were obtained through trial-specific data collection. Data on staff engagement and confidence with trial procedures were obtained via a bespoke questionnaire for the purpose of the SWAT. Questionnaires were sent via e-mail to individuals listed on the study contacts log, 3 months after each site opened to recruitment and comprised of 12 questions. Respondents were asked about their role (nurse or doctor with no research duties, allied health professional, research nurse, doctor with research duties, or 'other') and involvement in screening patients, randomising, consenting and involvement in clinical care of participants and their role in the delivery of the trial interventions. For the latter, respondents were also asked to score their level of confidence with each procedure on a five-point scale ranging from 'not at all confident' to 'extremely confident'. Respondents were also asked to provide an assessment of how well they felt the site initiation visit alone prepared them for their role in the study overall and ways in which the training for the study could be improved.

Study within a trial interventions

Sites randomised to the intervention received access to an online education and training package

in addition to a site initiation visit conducted by the Chief Investigator and co-ordinating trial team and associated materials. The online education and training package was accessed by individual members of staff at the participating sites via a bespoke study training website, with access granted to individual users by the Clinical Trials Unit. The education and training package included supplementary written materials to support the site initiation visit and materials, covering the trial's rationale and aims, patient eligibility, randomisation, intervention delivery, key contacts and additional resources. The sections on eligibility, randomisation and intervention delivery featured case studies with scenario-based vignettes and multiple-choice questions. Participants completing the online training were required to answer these questions to progress through the course. Immediate feedback was provided after each question, displaying the correct answer if the response was incorrect. Sites randomised to control received a site initiation visit conducted by the Chief Investigator and co-ordinating trial team and associated materials alone.

Outcomes

The primary outcome was protocol adherence to the randomised interventions defined as the number and percentage of patients with at least one protocol deviation recorded. Protocol deviations relating to the trial interventions were recorded over the first 7 days of treatment and defined for the main trial as:

- *Below target range deviations:* at least 4 consecutive hourly measurements (constituting 3 consecutive hours) where the patient's SpO₂ was below the target range and both the FiO₂ and mean airway pressure have stayed constant (or decreased) over all four observations.
- *Above target range deviation:* at least 4 consecutive hourly measurements (constituting 3 consecutive hours) where the patient's SpO₂ was above the target range and both the FiO₂ and mean airway pressure have stayed constant (or increased) over all four observations.

Other outcomes included levels of staff confidence with trial procedures measured by questionnaire.

Study within a trial results

TABLE 1 Summary of protocol non-adherence according to SWAT allocation

Deviation type	No enhanced training (N = 196)	Enhanced training (N = 164)
All deviations		
Patients with any deviation recorded, n (%)	37 (18.9)	41 (25.0)
Total number of deviations recorded, n	102	101
Hours of deviation over hours of invasive ventilation, n/N (%)	307/14,313 (2.1)	308/13,857 (2.2)
Above range deviations		
Patients with any deviation recorded, n (%)	30 (15.3)	22 (13.4)
Total number of deviations recorded, n	70	56
Hours of deviation over hours of invasive ventilation, n/N (%)	211/14,313 (1.5)	173/13,857 (1.2)
Below range deviations		
Patients with any deviation recorded, n(%)	8 (4.1)	19 (11.6)
Total number of deviations recorded, n	32	45
Hours of deviation over hours of invasive ventilation, n/N (%)	96/14,313 (0.7)	135/13,857 (1.0)

TABLE 2 Summary of protocol non-adherence according to SWAT allocation by site

	No enhanced training							Enhanced training						
	A	B	C	D	E	F	G	H	I	J	K	L	M	N
Patients randomised, n	11	23	22	99	6	5	30	31	11	25	12	34	39	12
All deviations														
Patients with any deviation recorded, n (%)	1 (9.1)	4 (17.4)	4 (18.2)	22 (22.2)	1 (16.7)	0 (0.0)	5 (16.7)	11 (35.5)	2 (18.2)	7 (28.0)	2 (16.7)	9 (26.5)	6 (15.4)	4 (33.3)
Total number of deviations recorded, n	2	13	17	52	2	0	16	16	19	9	4	33	15	5
Above range deviations														
Patients with any deviation recorded, n (%)	1 (9.1)	3 (13.0)	3 (13.6)	18 (18.2)	1 (16.7)	0 (0.0)	4 (13.3)	4 (12.9)	1 (9.1)	3 (12.0)	1 (8.3)	5 (14.7)	4 (10.3)	4 (33.3)
Total number of deviations recorded, n	1	12	7	34	2	0	14	6	10	5	2	16	12	5
Below range deviations														
Patients with any deviation recorded, n (%)	1 (9.1)	1 (4.3)	1 (4.5)	4 (4.0)	0 (0.0)	0 (0.0)	1 (3.3)	7 (22.6)	1 (9.1)	4 (16.0)	1 (8.3)	4 (11.8)	2 (5.1)	0 (0.0)
Total number of deviations recorded, n	1	1	10	18	0	0	2	10	9	4	2	17	3	0

TABLE 3 Site staff confidence with study procedures by SWAT allocation

	No enhanced training (N = 12)	Enhanced training (N = 8)
How confident do you feel with screening patients for the Oxy-PICU study?		
Not at all confident	0 (0.0)	0 (0.0)
Not so confident	0 (0.0)	0 (0.0)
Somewhat confident	1 (8.3)	0 (0.0)
Very confident	8 (66.7)	5 (62.5)
Extremely confident	3 (25.0)	3 (37.5)
N/A	0 (0.0)	0 (0.0)
How confident do you feel with randomising patients for the Oxy-PICU study?		
Not at all confident	0 (0.0)	0 (0.0)
Not so confident	0 (0.0)	0 (0.0)
Somewhat confident	1 (8.3)	1 (12.5)
Very confident	3 (25.0)	3 (37.5)
Extremely confident	7 (58.3)	4 (50.0)
N/A	1 (8.3)	0 (0.0)
How confident do you feel with following consent procedures for the Oxy-PICU study?		
Not at all confident	0 (0.0)	0 (0.0)
Not so confident	0 (0.0)	0 (0.0)
Somewhat confident	0 (0.0)	0 (0.0)
Very confident	5 (41.7)	2 (25.0)
Extremely confident	7 (58.3)	6 (75.0)
N/A	0 (0.0)	0 (0.0)
How confident do you feel with delivering care in line with the Oxy-PICU study for patients randomised to the conservative oxygenation target group?		
Not at all confident	0 (0.0)	0 (0.0)
Not so confident	0 (0.0)	0 (0.0)
Somewhat confident	0 (0.0)	1 (12.5)
Very confident	4 (33.3)	2 (25.0)
Extremely confident	2 (16.7)	2 (25.0)
N/A	6 (50.0)	3 (37.5)
How confident do you feel with delivering care in line with the Oxy-PICU study for patients randomised to the liberal oxygenation target group?		
Not at all confident	0 (0.0)	0 (0.0)
Not so confident	0 (0.0)	0 (0.0)
Somewhat confident	0 (0.0)	0 (0.0)
Very confident	2 (16.7)	1 (12.5)
Extremely confident	4 (33.3)	4 (50.0)
N/A	6 (50.0)	3 (37.5)
N/A, not applicable.		