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# Weaning children from the breathing machine in the children's intensive care unit

**Submission date**
11/12/2017

**Recruitment status**
No longer recruiting

**Registration date**
08/03/2018

**Overall study status**
Completed

**Last Edited**
27/01/2025

**Condition category**
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
A mechanical ventilator is a machine that helps people breathe when they are not able to breathe enough on their own. A new protocol has been developed for getting children off the ventilator (known as weaning). It is a series of steps that the care team need to follow and involves using a tool called the COMFORT scale to assess whether the sedation a child is receiving is suitable for them. It also includes using information from the ventilator to assess when it is time to check if the patient can come off the ventilator (extubation). In order to check whether the patient can come off the ventilator the protocol includes steps to check how well a child is able to breathe for themselves (while they are still on the ventilator). If this shows the patient is ready to come off the ventilator, the child is extubated using the PICU's usual practice (by trained clinical staff who are normally responsible for this). The aim of this study is to find out whether the new protocol can reduce the duration of mechanical ventilation and is cost effective compared with usual care.

Who can participate?
Children aged under 16 who are on ventilators in up to 18 Paediatric Intensive Care Units (PICUs) across the UK

What does the study involve?
At the start of the study, all PICUs continue to follow their current usual care practices for trying to get children off the ventilator (known as weaning). This is referred to as the 'control period'. Every month a PICU is randomly allocated to introduce the new protocol to try to get children off the ventilator as soon as it is safe to do so. Both doctors and nurses are involved in the steps to assess whether a child is ready to come off the ventilator. To help introduce this new approach to weaning and sedation, staff in PICUs are trained on what they have to do. An experienced nurse goes to all of the PICUs and trains a core team of staff (including the person who is normally responsible for arranging training for everyone). These staff subsequently arrange training for the other medical and nursing staff in their unit. The PICUs are also given training manuals and there is a training course that nurses and doctors can complete on the internet. All participating PICUs routinely collect data into a database known as PICANet which is

used to find out the best ways to treat and care for children. This study uses data collected by PICANet. In addition, other data is taken from patient's charts and medical notes and entered into a secure database by a member of the team who works for the PICU.

What are the possible benefits and risks of participating?
The protocol may lead to a benefit of a reduction in time on mechanical ventilation. During the spontaneous breathing test the patient may experience signs of respiratory distress. They will be monitored closely throughout by the clinical team and if there are signs of respiratory distress, patients will be returned to invasive mechanical ventilation.

Where is the study run from?
1. Alder Hey Children's Hospital (UK)
2. Royal Belfast Hospital for Sick Children (UK)
3. Birmingham Children's Hospital (UK)
4. Bristol Royal Children's Hospital (UK)
5. Royal Brompton Hospital (UK)
6. Addenbrooke's Hospital (UK)
7. Noah's Ark Children's Hospital for Wales (UK)
8. Great Ormond Street Hospital (UK)
9. Variety Children's Hospital (UK)
10. Leeds General Infirmary (UK)
11. Royal Victoria Infirmary (UK)
12. John Radcliffe Hospital (UK)
13. Southampton General Hospital (UK)
14. St George's Hospital (UK)
15. St Mary's Hospital (UK)
16. Royal Stoke University Hospital (UK)
17. Sheffield Children's Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2017 to May 2020

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Prof. Bronagh Blackwood

# Contact information

### Type(s)
Scientific

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Public

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## Additional identifiers

### ClinicalTrials.gov (NCT)
NCT03673683

### Protocol serial number
36228

## Study information

### Scientific Title
Sedation AND Weaning In CHildren: the SANDWICH trial

### Acronym
SANDWICH

### Study objectives
Cluster-randomised stepped wedge (SW) clinical and cost-effectiveness trial with an internal pilot and a process evaluation (PE), to determine if a protocol-based intervention, incorporating co-ordinated care with greater nursing involvement, to manage sedation and ventilator weaning can reduce the duration of invasive mechanical ventilation and is cost effective compared with usual care in children in Paediatric Intensive Care Units.

### Ethics approval required
Old ethics approval format

## Ethics approval(s)
East Midlands - Nottingham 1 Research Ethics Committee, 12/09/2017, ref: 17/EM/0301

## Study design
Randomised; Interventional; Design type: Process of Care, Complex Intervention

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Acute respiratory failure

## Interventions
This study will be conducted in up to 18 Paediatric Intensive Care Units (PICUs) across the UK. Each PICU will be considered a 'cluster' in this trial. All clusters will open and start the trial at the same time. At the beginning of the study, all clusters will continue to follow their current usual care practices for trying to get children off the ventilator (known as weaning). This is referred to as the 'control period'.

Every month a PICU will be randomized to the 'intervention'. The intervention involves the introduction of a new structured approach by a child's care team to try to get them off the ventilator as soon as it is safe to do so. Both doctors and nurses will be involved in the steps to assess whether a child is ready to come off the ventilator.

The Chief Investigator (CI) for the study gathered together a group of doctors and nurses from PICUs across the UK to get their advice on ways to improve how weaning and sedation is managed. Using the feedback from this meeting, the CI and other investigators involved in the study (consultants and nurses who work in PICUs) developed a 'protocol' for weaning. The protocol is a description of the steps that the care team need to follow. It involves using a tool called the
COMFORT scale to assess if the sedation a child is receiving is suitable for them. It also includes using information from the ventilator to assess when it is time to check if the patient can come off the ventilator (extubation). In order to check if the patient can come off the ventilator the protocol includes steps to check how well a child is able to breath for themselves (while they are still on the ventilator). If this shows the patient is ready to come off the ventilator, the child will be extubated using the PICUs usual practice (by trained clinical staff who are normally responsible for this).

To help introduce this new approach to weaning and sedation, staff in PICUs will be trained on what they have to do. An experienced nurse, who is part of the CI's team, will go to all of the PICUs and train a core team of staff (including the person who is normally responsible for arranging training for everyone). These staff will subsequently arrange training for the other medical and nursing staff in their unit. The PICUs will also be given training manuals and there will be a training course that nurses and doctors can complete on the internet.

At any one time in any unit, the same approach to weaning (usual-care or the new approach) will be followed for all mechanically ventilated children. For this reason, and because it is a low risk trial, a non-confirmed deemed consent (opt-out) approach will be taken. Leaflets will be

provided to parents of children, informing them that the PICU is involved in a study and that staff will be collecting anonymised patient level information during that time. Staff will not ask parent/guardians to confirm that they consent for their child's information to be used in the trial. The leaflets provided to parents will include details of who can be contacted to get more information or to ask that any information collected about their child is not included in the data analysis. Posters will also be displayed in prominent areas to raise awareness that the PICU is conducting a trial.

All participating PICUs routinely collect data into a database known as PICANet which is used to find out the best ways to treat and care for children. The SANDWICH trial will use data collected by PICANet. In addition, other data needed for the trial will be taken from patient's charts and medical notes and entered into a secure database by a member of the team who works for the PICU. No identifiable information will be collected or used during the trial.

Data will be collected, and included in data analysis, for all children admitted to participating PICUs except those who are expected to be on the ventilator for an indefinite length of time, and those whose parents/guardians opt-out of data collection. The number of children not included in the data analysis, and the reason why, will be recorded.

When PICUs are randomised to the intervention they will be given 2 months to prepare e.g. time to organise when staff will be available to complete their training. During the next 2 months staff will receive training on the intervention, after which, all staff at the PICU should follow the new approach to weaning; they will continue using the new approach for the rest of the trial.

The trial will also include a Process Evaluation (PE). PICU staff, who are involved in either implementing the training or delivering the intervention, will be approached by members of their local research team (Principal Investigator [PI], research nurse or champion), and invited to participate in the PE.

Participants will be chosen to ensure participation from a range of staff grades and professions. They will be provided with a written information leaflet which outlines the purpose of the research, what it involves, the benefits and whom they can contact if they require additional information. Staff will be given at least 24 hour to consider whether they wish to participate or not. The PE Researcher will subsequently contact those staff willing to participate in the PE to organise
individual and/or focus group interviews. Fully informed written consent will be obtained.

Initial PE visits will be scheduled in the months just prior to PICU training on the intervention. These interviews will establish the context and usual practice at each unit. During the final months of the study, the PE will explore with staff the factors that helped or hindered how well the quality improvement plan was delivered, implemented and embedded in units.

## Intervention Type
Other

## Primary outcome(s)
Duration of Invasive Mechanical Ventilation measured in hours through review of patient Intensive care charts from initiation of invasive ventilation until successful extubation (success defined as still breathing spontaneously 48 hours following extubation); Timepoint(s): 48 hours

## Key secondary outcome(s))

1. Incidence of successful extubation is measured through review of patient intensive care charts at 48 hours following extubation
2. Number of unplanned extubations is measured through review of patient intensive care charts up to 90 days or PICU discharge
3. Number of reintubations is measured through review of patient intensive care charts up to 90 days or PICU discharge
4. Total duration of Invasive Mechanical Ventilation in hours through review of patient intensive care charts up to 90 days or discharge
5. Incidence and duration in minutes of post extubation use of non-invasive ventilation is measured through review of patient intensive care charts up to 90 days or PICU discharge
6. Incidence of tracheostomy insertion is measured through review of patient intensive care charts at 90 days or PICU discharge
7. Incidence of post-extubation Stridor is measured through review of patient intensive care charts at 90 days or PICU discharge
8. Incidence of any adverse events is measured through review of patient notes at 90 days or PICU discharge
9. PICU length of stay is measured in days through review of patient notes at PICU discharge
10. Hospital length of stay discharge is measured in days through review of patients notes at hospital discharge
11. Incidence of mortality in ICU is measured through review of the PICAnet data set at PICU discharge
12. Incidence of mortality in hospital is measured through review of patients notes at hospital discharge
13. Cost per complication avoided is measured through review of patients notes and the PICAnet dataset at 28 days

### Completion date
15/05/2020

## Eligibility

### Key inclusion criteria
All invasively mechanically ventilated children < 16 years old

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Total final enrolment
10498

### Key exclusion criteria

1. Children who would not reach the primary endpoint

Added 15/05/2019:
2. Children who are pregnant, as documented in their medical notes

### Date of first enrolment
05/02/2018

### Date of final enrolment
14/10/2019

## Locations

### Countries of recruitment
United Kingdom

England

Northern Ireland

Wales

### Study participating centre
### Alder Hey Children's Hospital
Liverpool
United Kingdom
L12 2AP

### Study participating centre
### Royal Belfast Hospital for Sick Children
Belfast
United Kingdom
BT12 6BE

### Study participating centre
### Birmingham Children’s Hospital
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH

### Study participating centre

**Bristol Royal Children's Hospital**
Upper Maudlin Street
Bristol
United Kingdom
BS2 8BJ

**Study participating centre**
**Royal Brompton Hospital**
Sydney Street
London
United Kingdom
SW3 6NP

**Study participating centre**
**Addenbrooke's Hospital**
Hills Road
Cambridge
United Kingdom
CB2 0QQ

**Study participating centre**
**Noah's Ark Children's Hospital for Wales**
Cardiff
United Kingdom
CF14 4XW

**Study participating centre**
**Great Ormond Street Hospital**
Great Ormond Street
London
United Kingdom
WC1 N3JH

**Study participating centre**
**Variety Children's Hospital**
King's College Hospital
United Kingdom
SE5 9RS

**Study participating centre**
**Leeds General Infirmary**
Leeds
United Kingdom
LS1 3EX

**Study participating centre**
**Royal Victoria Infirmary**
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

**Study participating centre**
**John Radcliffe Hospital**
Headington
Oxford
United Kingdom
OX3 9DU

**Study participating centre**
**Southampton General Hospital**
Tremona Road
Southampton
United Kingdom
SO16 6YD

**Study participating centre**
**St George's Hospital**
Blackshaw Road
Tooting
London
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SW17 0QT

**Study participating centre**
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W2 1NY

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Newcastle Road
Staffordshire
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ST4 6QG

**Study participating centre**
**Sheffield Children's Hospital**
Western Bank
Sheffield
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S10 2TH

# Sponsor information

**Organisation**
Queen's University of Belfast

**ROR**
https://ror.org/00hswnk62

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health Research

**Alternative Name(s)**
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

## IPD sharing plan summary
Other

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 25/06/2021 | 25/06/2021 | Yes | No |
| Results article | results | 03/08/2021 | 04/08/2021 | Yes | No |
| Results article | Process evaluation | 27/11/2023 | 28/11/2023 | Yes | No |
| Protocol article | protocol | 10/11/2019 | 08/12/2020 | Yes | No |
| HRA research summary | | | 26/07/2023 | No | No |
| Other publications | Secondary analysis | 23/01/2025 | 27/01/2025 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |