

## ACUTE pilot trial safety reporting procedures and adverse events

### Flow chart detailing safety reporting procedures for the ACUTE study

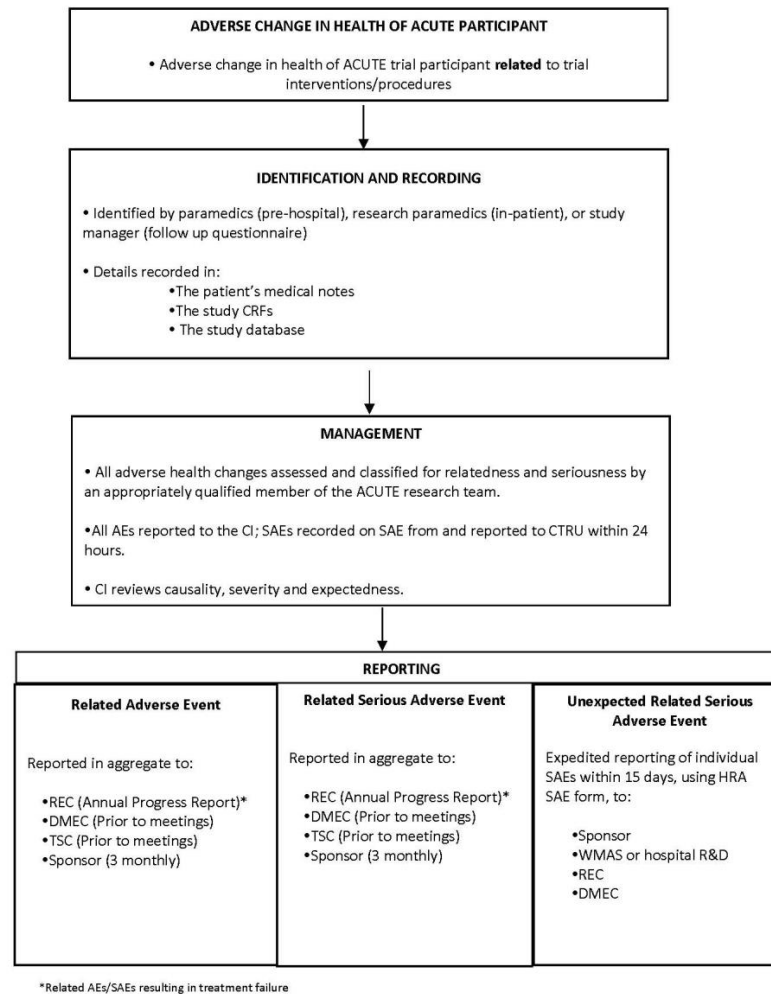


Table of classification of adverse events.

Adverse Health Change Terminology*	Definition
<b>Seriousness</b>	
<b>Adverse Event (AE)</b>	An adverse change in health that occurs while a patient is taking part in a study
<b>Serious Adverse Event (SAE)</b>	Any adverse event occurring while a patient is taking part in a study, that results in: <ul style="list-style-type: none"> <li>• Death</li> <li>• Life Threatening Illness</li> <li>• Hospitalisation</li> <li>• Prolongation of Hospitalisation</li> <li>• Disability or Incapacity</li> <li>• Congenital abnormality or birth defect</li> <li>• Other adverse health change resulting in inability to perform routine activities or significant medical event</li> </ul>
<b>Causality</b>	
<b>Unrelated</b>	An adverse change in health that occurs while a patient is taking part in a study which is not caused by or related to trial treatments.
<b>Related</b>	An adverse change in health that occurs while a patient is taking part in a study, which is caused by or related to trial treatments. An AE or SAE is considered related if the relationship between the event and trial treatments is: <ul style="list-style-type: none"> <li>• Possible - There is some evidence to suggest a causal relationship. However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant treatments).</li> <li>• Probable - There is evidence to suggest a causal relationship and the influence of other factors is unlikely, or</li> <li>• Definite - There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.</li> </ul>
<b>Expectedness</b>	
<b>Unexpected</b>	Any adverse health change that is <b>NOT</b> consistent with the known and expected adverse events of trial treatments i.e. it is not listed in the protocol or related documents/literature as an expected occurrence.
<b>Expected</b>	Any adverse health change that <b>IS</b> consistent with the known and expected adverse events of trial treatments
<b>Severity*</b>	
<b>Mild</b>	An adverse health change that does not interfere with routine activities
<b>Moderate</b>	An adverse health change that interferes with routine activities
<b>Severe</b>	An adverse health change that makes it impossible to perform routine activities

\*The term 'severity', is used to describe the intensity, and should not be confused with 'serious' which is based on participant/event outcome or action criteria. For example, a headache may be severe but not serious, while a minor stroke is serious but may not be severe.

**Table summary of the number of AEs and SAEs as well as the proportion of patients experiencing at least one AE or SAE for the ITT population**

	CPAP	Standard Oxygen Therapy	Total
Patients	42	35	77
Number of AEs	27	20	47
Number of individuals with an AE	23 (54.8%)	17 (48.6%)	40 (51.9%)
Number of SAEs	22	17	39
Number of individuals with a SAE	19 (45.2%)	15 (42.9%)	34 (44.2%)

**ACUTE pilot trial adverse events**

Site	AE summary	AE category	Start date	End date	Serious?	Expected SAE?
Stoke	Headache	Other	19/08/2017	19/08/2017	No	No
Stoke	Arrested prior to receiving intervention	Cardiorespiratory arrest	13/09/2017	13/09/2017	Yes	No
Lichfield	Respiratory arrest	Other	17/09/2017	17/09/2017	Yes	No
Lichfield	Died prior to approach	Cardiorespiratory arrest	18/09/2017	18/09/2017	Yes	No
Stoke	Fractured NOF	Other	18/10/2017		Yes	No
Erdington	Social Care readmission	Other	23/10/2017	08/12/2017	Yes	No
Lichfield	CVA	Other	28/10/2017	15/12/2017	Yes	No
Stafford	Death	Cardiorespiratory arrest	29/10/2017	29/10/2017	Yes	Yes
Stafford	Death	Cardiorespiratory arrest	29/10/2017	29/10/2017	Yes	Yes
Stoke	Pt died	Cardiorespiratory arrest	16/11/2017	16/11/2017	Yes	No
Stoke	Re-admission within 30 days	Other	30/11/2017	30/11/2017	No	Yes
Stoke	Claustrophobia	Claustrophobia	12/12/2017	12/12/2017	No	Yes
Erdington	Distress at mask	Other	15/12/2017	15/12/2017	No	Yes

Erdington	Died within 30 days	Cardiorespiratory arrest	21/12/2017	21/12/2017	Yes	No
Stafford	Pt died	Cardiorespiratory arrest	29/12/2017	29/12/2017	Yes	Yes
Stoke	Mild claustrophobia	Claustrophobia	05/01/2018	05/01/2018	No	Yes
Erdington	Readmission to respiratory ward with pneumonia	Other	05/01/2018	15/01/2018	Yes	Yes
Stafford	Re-admission	Other	10/01/2018		Yes	No
Stoke	Death	Cardiorespiratory arrest	14/01/2018	14/01/2018	Yes	Yes
Stoke	Pt died	Cardiorespiratory arrest	17/01/2018	17/01/2018	Yes	Yes
Stafford	Pt died on day of recruitment	Cardiorespiratory arrest	23/01/2018	23/01/2018	Yes	Yes
Stafford	Died ahead of 30 day follow up	Cardiorespiratory arrest	27/01/2018	27/01/2018	Yes	Yes
Stafford	Died on elderly care ward	Cardiorespiratory arrest	28/01/2018	28/01/2018	Yes	Yes
Stoke	Agitation and distress with mask	Progressive respiratory distress	28/01/2018	28/01/2018	No	Yes
Erdington	Death	Cardiorespiratory arrest	06/02/2018	06/02/2018	Yes	Yes
Stafford	Patient died	Cardiorespiratory arrest	20/02/2018	20/02/2018	Yes	Yes
Lichfield	Died prior to 30 day	Cardiorespiratory arrest	03/03/2018	03/03/2018	Yes	Yes
Stafford	Pt re-admitted to hospital during 30-day period after recruitment	Other	08/03/2018	15/03/2018	Yes	Yes
Lichfield	Died prior to approach	Cardiorespiratory arrest	09/03/2018	09/03/2018	Yes	Yes
Erdington	Died following discharge prior to approach	Cardiorespiratory arrest	10/03/2018	10/03/2018	Yes	Yes
Lichfield	Died prior to approach	Cardiorespiratory arrest	17/03/2018	17/03/2018	Yes	Yes

Stoke	Pneumothorax	Tension pneumothorax	28/03/2018	28/03/2018	Yes	Yes
Stoke	Patient got worse	Vomiting	28/03/2018	28/03/2018	No	Yes
Stafford	Pt re-admitted, then died	Other	12/04/2018	15/04/2018	Yes	Yes
Lichfield	Mask wouldn't inflate	Other	17/04/2018	17/04/2018	No	No
Lichfield	Cardiac arrest	Cardiorespiratory arrest	08/05/2018	08/05/2018	Yes	Yes
Lichfield	Death	Cardiorespiratory arrest	31/05/2018	31/05/2018	Yes	Yes
Stafford	Died prior to approach	Cardiorespiratory arrest	03/06/2018	03/06/2018	Yes	Yes
Lichfield	Readmissions within 30 days	Other	30/06/2018	01/07/2018	Yes	Yes
Lichfield	Readmission within 30 days	Other	02/07/2018	06/07/2018	Yes	Yes
Lichfield	Claustrophobia and Progressive Respiratory Distress	Other	05/07/2018	05/07/2018	No	Yes
Lichfield	Pneumothorax	Other	05/07/2018	27/07/2018	Yes	Yes
Stafford	Re-admission	Other	06/07/2018		Yes	Yes
Lichfield	Readmission	Other	07/07/2018	27/07/2018	Yes	Yes
Stoke	Pt re-admitted during 30-day reference period	Other	25/07/2018	03/08/2018	Yes	Yes
Lichfield	Readmission	Other	28/07/2018		Yes	Yes
Stoke	Death	Cardiorespiratory arrest	22/08/2018	22/08/2018	Yes	Yes