British Thoracic Society

Quality Standards for Non-invasive ventilation

Draft for public consultation

Available for public consultation from 1st August 2017 to 13th September 2017.

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A response form is available on the BTS website.
Please send your responses to Louise Preston by 5pm on Wednesday 13th September

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Quality Standards for Non-Invasive Ventilation

Draft for public consultation

The British Thoracic Society (BTS) has been at the forefront of the production of Guidelines for best clinical practice in respiratory medicine since the Society was established over 30 years ago. The Society was awarded NICE Accreditation for its guideline production process in November 2011 and the Society's Guideline Production Manual [1] setting out the detailed methodology and policy to produce guidelines is reviewed annually by the BTS Standards of Care Committee (SOCC).

A statement on quality standards based on each BTS Guideline is a key part of the range of supporting materials that the Society produces to assist in the dissemination and implementation of a Guideline's recommendations.

A quality standard is a set of specific, concise statements that:

- act as markers of high-quality, cost-effective patient care across a pathway or clinical area, covering treatment or prevention.
- are derived from the best available evidence.

NICE Quality Standards and the NICE Quality Standards Process Guide [2] were used as a model for the development of BTS Quality Standards.

This document contains the BTS Quality Standards for Non- Invasive Ventilation (NIV) in adults.

The rationale for these quality standards is drawn from evidence and recommendations summarised in the BTS Guidelines for the Ventilatory Management of Acute Hypercapnic Respiratory Failure [(3)] and is informed by the 2017 NCEPOD report on Non-invasive ventilation (NIV), 'Inspiring Change' [(4).]

The purpose of the Quality Standards document is to provide commissioners, healthcare professionals, planners and patients with a guide to standards of care which should be met for provision of acute NIV in the UK, together with measurable markers of good practice.

BTS quality standards are intended for:

- **Health care professionals,** to allow decisions to be made about care based on the latest evidence and best practice.
- **People who receive NIV**, to enable understanding of what services they should expect from their health care provider.
- **Service providers,** to be able to quickly and easily examine the clinical performance of their organisation and assess the standards of care they provide.
- **Commissioners,** so that they can be confident that the services they are purchasing are high quality and cost effective.

Method of Working

A Quality Standards Working Group was convened in February 2017 and met in May 2017, with the following membership:

Name	Location/organisation
Dr Mike Davies, Chair	Consultant Respiratory Physician Papworth, Cambridge BTS NIV Clinical Audit lead, Chair, BTS Critical Care SAG
Dr Martin Allen	Consultant Respiratory Physician, Stoke RCP London representative BTS Quality Improvement Committee
Dr Ben Creagh-Brown	Consultant Physician – Intensive Care Medicine Royal Surrey County Hospital, Guildford
Dr Ravi Mahadeva	Consultant Respiratory Physician Addenbrooke's, Cambridge
Dr Stephen Bourke	Consultant Respiratory Physician Northumbria Chair, BTS COPD SAG
Ian Setchfield	Acute care nurse consultant East Kent Hospitals University NHS Foundation Trust Society of Acute Medicine
Rachael Moses Physiotherapist	Consultant Respiratory Physiotherapist Lancashire Teaching Hospital
Dr Rachel D'Oliveiro	ST/ICM trainee Ipswich
Dr Andrew Bentley	Intensive Care Society
Professor Alasdair Gray	Royal College of Emergency Medicine
Dr Phillip Jacobs	Society for Acute Medicine
Dr Alastair Glossop	Royal College of Anaesthetists

Members of the Quality Standards Group submitted Declaration of Interest forms in line with the BTS Policy and copies of forms are available on request from BTS Head Office.

The draft document was considered in detail by the BTS Standards of Care Committee and the BTS Quality Improvement Committee initially in June 2017.

The document was made available on the BTS website for public consultation for the period from 1st August to 13th September 2017.

Following further revision, the document was submitted for approval to the BTS Standards of Care Committee in [date tbc]

The Quality Standards document will be reviewed in [date tbc] or following the publication of a revised Guideline whichever is the sooner.

Each Quality Standard includes the following:

- A **Quality Statement,** which describes a key marker of high-quality, cost-effective care for this condition.
- **Quality Measures**, which aim to improve the structure, process and outcomes of health care.

The quality measures are not intended to be new sets of targets or mandatory indicators for performance management that need to be collected. The quality measures are specified in the form of a numerator and a denominator, which define a proportion or ratio (numerator/denominator). It is assumed that the numerator is a subset of the denominator population. The suggested numerator and denominator are provided to allow healthcare professionals and service providers to examine their clinical performance in relation to each quality standard. It is recognised that no national quality indicators will be available for this condition, and institutions will need to agree locally what information is required for the denominator to be used in each case, and what the expected level of achievement should be, given local circumstances. A brief description about the quality standard in relation to each audience is given.

The main source references for these quality standards are:

BTS/ICS Guidelines for the Ventilatory Management of Acute Hypercapnic Respiratory Failure in Adults (2016)[(3)].

National Confidential Enquiry into Patient Outcome and Death. Inspiring Change. London: NCEPOD; 2017[(4)].

There is no specific order of priority associated with the list of quality statements.

Quality statement 1- Acute non-invasive ventilation (NIV) should only be carried out in specified clinical areas designated for the delivery of NIV.

Quality statement 2 - All staff who prescribe, initiate, or make changes to acute NIV treatment should have evidence of training and maintenance of competencies appropriate for their role.

Quality statement 3 - Acute NIV should be offered to all patients who meet evidence-based criteria on presentation. Hospitals must ensure that adequate systems, staffing, and capacity are in place to provide NIV to all eligible patients.

Quality statement 4 - Patients who meet evidence-based criteria for acute NIV on admission should start NIV within 120 minutes of hospital arrival. In patients who develop acute hypercapnic respiratory failure (AHRF) after admission, NIV should be commenced within 120 minutes of the first blood gas showing AHRF.

Quality statement 5 - All patients treated with acute NIV should have blood gas analysis performed at one and four hours after initiation; failure of these blood gas measurements to improve should trigger an adjustment to NIV therapy and/or specialist review within 30 minutes.

Quality statement 6 - All patients treated with acute NIV should have a timely and ongoing medical review and a documented escalation plan.

Quality Statement 1

Acute non-invasive ventilation (NIV) should only be carried out in specified clinical areas designated for the delivery of NIV.

Rationale:
Acute NIV is delivered as a ward-based service for most patients treated in the UK. National audit data confirm that patients treated with NIV should be considered at high risk of death; national averages for in-hospital mortality exceed 30%. Use of NIV in non-specialised areas is associated with poorer outcomes; in the most recent BTS audit (2013), patients who started NIV in general medical wards experienced the highest mortality rate, when compared to NIV starting in other areas [(5)].

Levels of trained staff, patient monitoring, and near-patient point of care testing must be sufficient to manage such patients effectively. Accepting that there are differences in hospital size and provision, defining appropriate areas for NIV is the function of a local operational policy. Nevertheless, there are some key infrastructure requirements that are uniform regardless of location for NIV treatment. These are provided in appendix 1.

Areas should be specified according to their capacity to provide effective NIV care, not the name of the area. Suitable areas may include emergency departments (ED), acute medical units, respiratory wards, high dependency units and critical care.

The severity of acute (acidaemic) hypercapnic respiratory failure (AHRF) and evidence of other organ dysfunction should influence the choice of care environment and staffing requirement.

This quality statement links to recommendations 6 and 7 of the NCEPOD 'Inspiring Change' report.

Quality measure:
Structure:
Evidence of local arrangements to ensure that NIV is delivered in clinical areas that are specified in local operational policy.
Process:
Proportion of adults who receive NIV care in an appropriate clinical area as defined in a local operational policy. This area should meet the recommendations of the BTS/ICS Guidelines for the Ventilatory Management of Acute Hypercapnic Respiratory failure in Adults (2016)[(3)] and NCEPOD's 'Inspiring Change' report.[(4)]

Numerator 1:
Number of patients who start NIV in a designated NIV area* of the hospital.
Denominator 1:
Total number of patients treated with NIV.
Numerator 2:
Number of patients who receive continuous oximetry monitoring during the first 24 hours of NIV.
Denominator 2:
Total number of patients treated with NIV.

*A hospital's local operational policy must specify appropriate clinical areas for NIV. Designated NIV areas must meet all key infrastructure requirements as defined in appendix 1. Dedicated outreach teams may start NIV prior to transfer to an NIV area, providing that patients receive the same provision of staffing and monitoring. Transfer to an appropriate area should occur within four hours. If these criteria (appendix 1 and/or transfer) are not met, then the patient should not be included in numerator 1.

What the quality statement means for each audience

Service providers:

- Ensure systems are in place for all appropriate patients to be treated with NIV in an appropriate clinical area. This includes specifying clinical and operational pathways to ensure that such areas are identified and provide sufficient ventilators, masks and monitoring equipment to meet the expected demands of the service, and that such clinical areas have an appropriate trained staff / patient ratio (as set out in appendix 1).

Healthcare professionals:

- Ensure that patients treated with NIV are cared for in an appropriate clinical area. Senior healthcare professionals should work with operational managers to ensure that their NIV service meets BTS/ICS criteria and NCEPOD recommendations (appendix 1).

Commissioners:

- Ensure they commission acute NIV services that can demonstrate clinical pathways and service provision capable of providing effective delivery of care.

People who receive acute NIV:

- Should only be cared for in an appropriate clinical area that is configured to provide safe, effective care.

Relevant existing indicators:

BTS/ICS Guidelines for the Ventilatory Management of Acute Hypercapnic Respiratory Failure in Adults (2016).[3]

National data sources:

National Confidential Enquiry into Patient Outcome and Death. Inspiring Change. London: NCEPOD; 2017.[4]

BTS National NIV audit, 2010 – 2013. [5]

Source references:

BTS/ICS Guidelines for the Ventilatory Management of Acute Hypercapnic Respiratory Failure in Adults (2016). [3]

Other information:

Appendix 1 – NIV service infrastructure checklist.

Quality Statement 2

All staff who prescribe, initiate, or make changes to acute NIV treatment should have evidence of training and maintenance of competencies appropriate for their role.

Rationale:

NIV is an effective treatment provided it is delivered correctly. Key to this is training of staff to ensure they have both the knowledge and the practical skills commensurate with their role.

NCEPOD's study [4] highlights important deficiencies in the provision of training in the practical application of NIV treatment:

- 18% of hospitals did not have a defined staff competency assessment for the delivery of NIV.
- 37% of hospitals that had a formal competency framework permitted untrained staff to supervise patients on NIV.
- Overall, 45% of hospitals permitted staff without competency to directly supervise the care of patients receiving NIV.

The NCEPOD study did not investigate the level of training or competence of medical staff involved in the care of patients treated with NIV. However, important concerns were raised around clinical decision-making and overall care.

For some services, practical application of NIV and adjustment of ventilator settings are not within the remit of the on-call medical staff. Nevertheless, clinical responsibility requires a clear understanding of physiological principles, the evidence supporting the use of NIV, and decision-making in non-responders. Doctors at ST3+ grade usually represent the first line in clinical decision-making for patients treated with NIV; when required, training should be provided within induction for all doctors involved (including FY grades).

Evidence of competence should be documented within the training record (ePortfolio) for trainees or within the mandatory training record for all consultants who provide clinical input into the NIV service (including on-call input and for all locations of care).

This quality statement links to recommendation 8 of the NCEPOD 'Inspiring Change' report. [4]

Quality measure:

Structure:

Evidence that the practical delivery of NIV is only delivered by staff who are competent to do so and that individuals with clinical responsibility demonstrate competence in NIV clinical decision-making.

Process:

Percentage of staff delivering NIV with evidence of training / competencies together with evidence of annual updates.

Numerator 1: Number of healthcare professionals* with direct responsibility to initiate and make changes to NIV treatment who have evidence of competence in the practical use of NIV.

Denominator 1: Total number of healthcare professionals with direct responsibility to initiate and make changes to NIV treatment.

Numerator 2: Number of healthcare professionals with responsibility for the clinical decision to start NIV who have evidence of competence in the theory and practice of acute NIV treatment.

Denominator 2: Total number of healthcare professionals with responsibility for the clinical decision to start NIV.

* *healthcare professional = nursing / physiotherapy / medical / technical.*

What the quality statement means for each audience:

Service providers:

- Should ensure that **all** staff delivering NIV are competent to do so with evidence of initial training and annual updates. This should be provided via a mandatory rolling competency assessment commensurate with the role undertaken (i.e. practical delivery of NIV vs. clinical decision-making vs. both components). Service providers should ensure that training and competency assessments are standardised for all areas in which NIV is delivered, recognising that NIV services typically span across multiple clinical divisions. The Lead for service should be supported in mandating training across the whole trust.

Healthcare professionals:

- Who are both caring for and initiating NIV should have evidence that they are being trained in the theory and practice of NIV, commensurate of their role.

Commissioners:

- Should ensure that any service commissioned to provide acute NIV has staff who are trained, competent and receive annual knowledge updates.

People who receive acute NIV:

- Should have this delivered by trained and competent staff, commensurate with their role in the service.

Relevant existing indicators:

BTS/ICS Guidelines for the Ventilatory Management of Acute Hypercapnic Respiratory Failure in Adults (2016).[3]

National data sources:

National Confidential Enquiry into Patient Outcome and Death. Inspiring Change. London: NCEPOD; 2017.[4]

Source references:

BTS/ICS Guidelines for the Ventilatory Management of Acute Hypercapnic Respiratory Failure in Adults (2016). [3]

Other information:

Appendix 2 – NIV service staff training checklist

Quality Statement 3

Acute NIV should be offered to all patients who meet evidence-based criteria on presentation. Hospitals must ensure that adequate systems, staffing, and capacity are in place to provide NIV to all eligible patients.

Rationale:

For COPD exacerbations complicated by AHRF, NIV reduces mortality two-fold. [6,7] However, the CAOS study showed that 80% of clinician estimates of outcome were unduly nihilistic. [8,9] There was marked variation in the baseline characteristics of ventilated patients between units, including age and performance status.[10] The 2014 COPD audit showed that 50% of patients with AHRF on their first blood gas and 34% of those with persistent or new respiratory acidaemia on serial blood gas did not receive NIV.[10]

Non-randomised studies also show that NIV provides benefit for patients with AHRF in association with obesity hypoventilation, chest-wall disorders and neuromuscular disease.

The discussion with patients should take account of their stable state performance status, other clinical indices that may influence outcome, and patient wishes. However poor performance status alone should not be considered an exclusion criterion for NIV.

Failure to provide NIV when it is indicated increases length of stay and hospital mortality. This represents an omission of care and places the patient concerned at risk of moderate or serious harm. Measures should be in place via routine clinical governance to review all cases of morbidity and mortality associated with NIV. This includes escalation to investigation as a Serious Incident if omission of care is believed to have caused unexpected or avoidable death. This is the rationale for quality measure 2 in this standard. It aims to quantify the number of patients who were not treated with NIV due to a non-clinical reason, such as an insufficient capacity of trained staff, NIV ventilators or beds on an appropriate unit.

Quality measure:

Structure:

Acute hospitals and trusts should ensure:

- Patients who meet evidence-based criteria are offered NIV.
- The decision whether to initiate NIV should be based on objective review by, and an informed discussion with, a clinician with appropriate expertise.
- NIV may be provided in other conditions lacking a similar evidence base, provided senior review involving a specialist has taken place.
- There should be sufficient trained staff, ventilators and bed capacity in appropriate areas to provide NIV when required.
- There is a robust governance structure that investigates acts or omissions in care.

Process: Proportion of patients with an evidence-based indication for NIV who are treated with NIV. Measure 1 quantifies patients with COPD alone on the basis that they represent the most frequent indication for NIV and are easier to define (as a single patient population). Measure 2 quantifies all patients not treated with NIV who, on review (e.g. Morbidity and Mortality review), should have been treated with NIV.

Numerator 1: Number of patients with COPD exacerbation and a clinical indication for NIV* who are treated with NIV.

Denominator 1: Number of patients with COPD exacerbation and a clinical indication for NIV*.

** excluding patients who show full resolution of respiratory acidaemia following a one hour trial of controlled oxygen and medical optimisation, but Including all patients who: a) decline NIV following a*

documented informed discussion, b) proceed direct to invasive ventilation or c) in whom a senior specialist has confirmed that NIV or invasive ventilation would be futile.

Numerator 2: Number of patients with a clinical indication for NIV who are not treated with NIV.**
Denominator 2: Number of patients with a clinical indication for NIV who are treated with NIV.
*** excluding patients who: a) decline NIV following a documented informed discussion, b) receive invasive ventilation or* c) in whom a senior specialist has confirmed that NIV or invasive ventilation would be futile.

What the quality statement means for each audience:
Service providers:
- must ensure there are adequate systems, staffing, and capacity in place to provide NIV to all eligible patients. Service providers should ensure that there is a robust and responsive clinical governance process if NIV is not provided when it is clinically indicated.

Healthcare professionals:
- should ensure that patients with a clinical need for NIV are reviewed by a clinician with appropriate expertise and are offered NIV as indicated.

Commissioners:
- ensure that they commission services with sufficient capacity to provide NIV to all patients with a clinical indication for NIV.

People who receive NIV:
- should not have access to treatment restricted due to undue nihilism or lack of capacity. The decision to initiate NIV should be supported by a discussion with a clinician with appropriate expertise and include an objective estimate of outcome should NIV be provided.

National data sources:
Stone RA, Holzhauer-Barrie J, Lowe D, et al. Who cares matters. National Chronic Obstructive Pulmonary Disease (COPD) Audit Programme: Clinical audit of COPD exacerbations admitted to acute units in England and Wales 2014. London: RCP; 2015. [(10)]

Source references:
Lightowler JV et al. Non-invasive positive pressure ventilation to treat respiratory failure resulting from exacerbations of chronic obstructive pulmonary disease: Cochrane systematic review and meta-analysis. *BMJ*. 2003;326(7382):185. [(6)]
Plant PK, Owen JL, Elliott MW. Early use of non-invasive ventilation for acute exacerbations of chronic obstructive pulmonary disease on general respiratory wards: a multicentre randomised controlled trial. *Lancet*. 2000; 3;355(9219):1931-5. [(7)]
Wildman MJ, Sanderson C, Groves J, et al. Implications of prognostic pessimism in patients with chronic obstructive pulmonary disease (COPD) or asthma admitted to intensive care in the UK within the COPD and asthma outcome study (CAOS): multicentre observational cohort study. *BMJ*; 2007;335.1132. [(8)]
Wildman MJ, Sanderson CF, Groves J, et al. Survival and quality of life for patients with COPD or asthma admitted to intensive care in a UK multicentre cohort: the COPD and Asthma Outcome Study (CAOS). Thorax 2009;64:128-32. [(9)]
BTS/ICS Guidelines for the Ventilatory Management of Acute Hypercapnic Respiratory Failure in Adults (2016). [(3)]
National Confidential Enquiry into Patient Outcome and Death. Inspiring Change. London: NCEPOD; 2017. [(4)]

Quality Statement 4

Patients who meet evidence-based criteria for acute NIV on admission should start NIV within 120 minutes of hospital arrival. In patients who develop AHRF after admission, NIV should be commenced within 120 minutes of the first blood gas showing AHRF.

Rationale:

Consensus expert opinion is that prompt application of NIV substantially reduces the risk of death in appropriately selected patients with AHRF.[6,7,9] Changes in respiratory rate and heart rate are indicators of risk. Delays in starting NIV are likely to worsen the degree of acidaemia prior to NIV which, in turn, is associated with a poorer outcome.[4,5]

The National Institute for Health and Clinical Excellence (NICE)[11] and NCEPOD[12] recognise the importance of immediate physiological assessment of acutely ill patients and recommend the use of physiological track and trigger systems to triage and assess. The National Early Warning Score (NEWS) is recommended by the Royal College of Physicians.

The NCEPOD 'Inspiring Change' study showed;

- Early warning scores were not used in 47% of patients treated with NIV.
- When used, 56% of patients had a NEWS score of 6 or more, indicating the need for urgent clinical assessment.

Failure of initial triage may lead to delays in undertaking the initial blood gas sample, and subsequent delays in starting effective treatment. Minimum time to assessment and treatment targets are commonplace in ED and serve to prioritise interventions most likely to improve outcomes. This statement intends to establish recognition and treatment of AHRF as a time-critical event in ED (and the wider hospital) without bypassing the necessity for specialist clinical decision-making.

Evidence-based criteria include a trial of medical therapy including controlled oxygen and drugs, and should still be retained provided the patient is not in extremis. However, this should be limited to one hour. This provides sufficient time for appropriate clinical assessment to ensure that the patient meets evidence-based criteria for treatment with acute NIV.

This statement does not define the nature of the blood gas measurement (arterial vs. capillary vs. venous). There are strengths and limitations for each approach, and these also vary according to the clinical situation. An arterial blood gas is the gold standard against which other methods are compared. As such, the arterial method is recommended for blood gas measurement that defines the physiological requirement for NIV (i.e. after the trial of medical therapy). At other times, other methods may provide advantages such as easier access and reduced pain.

This quality statement links to recommendation 5 of the NCEPOD 'Inspiring Change' report, which states that NIV should start within a maximum of one hour of the blood gas measurement that identified the need for it.'

Quality measure:

Structure:

Evidence of local arrangements to ensure that all patients meeting evidence based criteria for NIV therapy are treated in a timely fashion, including:

- Rapid clinical assessment to establish presence of respiratory distress or requirement for supplemental oxygen.

- Performing a blood gas measurement within one hour of arrival to the emergency department in patients with respiratory distress.
- Recognition of qualifying blood gas criteria for treatment with NIV.
- Understanding of evidence- based criteria for starting treatment with NIV.
- Starting NIV within 60 minutes of blood gas confirmation that NIV is clinically indicated in those patients meeting evidence -based criteria.

Process:

Proportion of patients treated with acute NIV (after appropriate and timely initial investigation) who start treatment with NIV within 120 minutes of hospital arrival or, for inpatients who experience late deterioration, within 120 minutes of the first blood gas result that confirms AHRF.

Numerator 1: Number of patients meeting evidence-based criteria for acute NIV who are treated with NIV within 120 minutes of admission or, for inpatients who develop AHRF at a later stage, within 120 minutes of the first blood gas showing AHRF.

Denominator 1: Total number of patients meeting evidence-based criteria for acute NIV who are treated with NIV.

Numerator 2: Number of patients treated with NIV whose first blood gas measurement is performed within 60 minutes of admission.

Denominator 2: Total number of patients who present with AHRF on admission who are treated with NIV.

What the quality statement means for each audience:

Service providers:

- ensure there are operational systems in place to ensure timely, effective triage and treatment with NIV, with accurate and reliable recording of the time of the following events for patients treated with NIV: ED arrival, point of care blood gas analysis, time of starting treatment with NIV. Providers are also required to support audit and data collection, plus mechanisms for feedback and quality improvement.

Healthcare professionals:

- ensure that they are adequately trained in the recognition of AHRF via clinical and blood gas parameters and understand the evidence-based criteria for treatment with NIV.

Commissioners:

- ensure that services are commissioned with sufficient available resources to establish acute NIV services that achieve prompt treatment as specified.

People who receive NIV:

- are promptly recognised and treated with an evidence-based intervention to improve outcomes in AHRF.

Source references:

Hill NS, Brennan J, Garpestad E, Nava S. Noninvasive ventilation in acute respiratory failure. *Crit Care Med*. 2007;35(10):2402-7.

National Institute for Health and Clinical Excellence. Acutely ill patients in hospital: recognition of and response to acute illness in adults in hospital 2007. (NICE clinical guideline No 50.). [11]

National Confidential Enquiry into Patient Outcome and Death. An acute problem? A report of the national confidential enquiry into patient outcome and death (NCEPOD) London: NCEPOD, 2005. [12]

National Confidential Enquiry into Patient Outcome and Death. Inspiring Change. London: NCEPOD; 2017. [4]

BTS/ICS Guidelines for the Ventilatory Management of Acute Hypercapnic Respiratory Failure in Adults (2016). [3]

Quality Statement 5

All patients treated with acute NIV should have blood gas analysis performed at one and four hours after initiation; failure of these blood gas measurements to improve should trigger specialist review within 30 minutes.

Rationale:
In addition to continuous monitoring of oxygen saturations and measurement of respiratory rate, blood gas sampling is used to assess the response to NIV. Routine analysis at one and four hours after starting treatment with NIV is recommended, with additional sampling in the event of clinical deterioration.[3]

Studies show that improvements in pH and $PaCO_2$ values, and a reduction in respiratory rate after two hours of NIV are strong predictors of treatment success [13]; conversely, failure of physiological improvement is associated with poor outcome.

NCEPOD's 'Inspiring Change' study[4] provides evidence of inadequate patient monitoring; case-note reviewers found that blood gas sampling was too infrequent for 32% and that overall monitoring could have been improved for 54% of patients treated with NIV. Where sampling took place, the clinical response was often suboptimal; ventilator management after initial set-up was rated as inappropriate for 35% of patients. Clinical review did not take place for 31% of patients who deteriorated while treated with NIV.

Failure to improve after four hours of appropriately instituted treatment requires specialist review (link to QS6).

This quality statement therefore aims to quantify key blood gas measurements and the response to these results.

Quality measure:
Structure:
Evidence that all patients treated with NIV have a routine blood gas performed at least at one and four hours to establish their response to therapy. Failure of these blood gas results to improve (pH the same or worse / or $PaCO_2$ the same or worse) should trigger specialist review within 30 minutes. A specialist is a healthcare professional with the necessary responsibility and NIV competence to make clinical decisions, including ST3+ doctor/specialist respiratory nurse practitioner / physiotherapist.
Process:
Proportion of patients treated with NIV who have a blood gas at the specified times, and the proportion of those whose blood gas reveals a failure to improve and are not seen by an appropriately trained specialist within 30 minutes.

Numerator 1: Number of patients who have a blood gas 30-90 minutes after starting treatment with NIV.
Denominator 1: Total number of patients treated with NIV.
Numerator 2: Number of patients who have a blood gas three - five hours after starting treatment with NIV.
Denominator 2: Total number of patients treated with NIV.
Numerator 3: Number of occasions when specialist review takes place within 30 minutes in response to a one or four-hour blood gas result that fails to improve in comparison to the prior sample.
Denominator 3: Number of occasions in which there is a one or four-hour blood gas result that fails to improve in comparison to the prior sample.

Failure to improve = pH the same or worse / or $PaCO_2$ the same or worse.

What the quality statement means for each audience:

Service providers:

- ensure that all sites with a NIV service must have a local operational policy that explicitly describes:
    - A system that delivers timely blood gas analysis.
    - Clear pathways to enable prompt upward titration of ventilation pressures and troubleshooting common ventilator or mask-related issues.
    - Access to a specialist able to review patients treated with NIV within 30 minutes if needed.
    - A method to record the time the specialist is called and attends, and a means to record their assessment and changes in management.

Healthcare professionals:

- ensure that the response to NIV is assessed early. Furthermore, the treating clinician should have access to an appropriate specialist colleague in a timely fashion to maximise the chance of delivering optimal care.

Commissioners:

- ensure that commissioned services have local policies and standards of care that will facilitate timely identification of patients whose treatment needs to be changed.

People who receive NIV:

- will be assessed by a qualified healthcare professional within a short period of time if initial treatment is not having the desired effect.

National data sources:

BTS National NIV audit, 2010 – 2013. [5]

National Confidential Enquiry into Patient Outcome and Death. Inspiring Change. London: NCEPOD; 2017. [4]

Source references:

Confalonieri M et al, A chart of failure risk for noninvasive ventilation in patients with COPD exacerbation. *Eur Respir J*. 2005;25(2):348-55.[13]

BTS/ICS Guidelines for the Ventilatory Management of Acute Hypercapnic Respiratory Failure in Adults (2016). [3]

Quality statement 6

All patients treated with acute NIV should have a timely and ongoing medical review and a documented escalation plan.

Rationale:

There is a high mortality in this patient population and the initial response to NIV provides key insights into treatment outcome. Failure to demonstrate at least partial physiological improvement after two hours of therapy is associated with poorer outcomes [13] and should prompt the need to consider invasive ventilation at this stage. [8,9]

Delivering effective care therefore requires clear escalation plans at the onset of NIV treatment, with access to consultant-level specialist support in the event of any uncertainty. [3] The initial escalation decision should be reviewed at the time of the first consultant review within 14 hours of admission.

This quality statement links to recommendations 9 and 10 of the NCEPOD 'Inspiring Change' report [4], and recommendations 2 and 3 of the Clinical Quality Indicators for Acute Medical Units (Society for Acute Medicine, 2011) [14].

An example of an escalation plan for acute NIV is attached. Many trusts already use generic documents, including Treatment Escalation Plans (TEP) and Universal Forms of Treatment Options (UFTO). These have the same aim as an NIV-specific document and would comply with this quality statement if the appropriate sections are completed.

Quality measure:

Structure:

Evidence of local arrangements to ensure that all patients treated with NIV should have:

- A documented escalation plan encompassing appropriateness of invasive ventilation, ceiling of treatment, and CPR status before starting NIV.
- Documented discussion with a specialist competent in the management of acute NIV at the time treatment is started or at the earliest opportunity afterwards.
- Specialist* review within 4 hours of initiation of NIV.
- Consultant clinical review including escalation status within 14 hours of starting NIV. **

*A specialist is a healthcare professional with the responsibility and necessary NIV competence to make clinical decisions, including ST3+ doctor/specialist respiratory nurse practitioner / physiotherapist.

** Consistent with national recommendations for acute medical care, consultant review for patients arriving 08.00am -18.00pm should usually be undertaken within 8 hours, with provision for earlier review according to clinical need.

Process:

Proportion of patients treated with NIV who have appropriate and timely clinical reviews including documented escalation plans.

Numerator 1: Number of patients with evidence of specialist review and a documented escalation plan within 4 hours of starting treatment with NIV.
Denominator 1: Total number of patients treated with NIV.
Numerator 2: Number of patients with evidence of consultant review and a documented escalation plan within 14 hours of starting treatment with NIV.
Denominator 2: Total number of patients treated with NIV.

What the quality statement means for each audience:

Service providers:

- should ensure there are systems in place to provide specialist review within four hours, consultant review within 14 hours and to use TEPs/UFTOs to document escalation decisions.

Healthcare professionals:

- should ensure that only appropriately trained specialists (up to consultant level) make clinical decisions for patients treated with NIV.

Commissioners:

- should ensure they commission acute NIV services that can demonstrate clinical pathways and service provision capable of providing effective delivery of care.

People who receive NIV:

- should be reviewed in a timely manner by senior clinicians with the necessary expertise to determine appropriate ceilings of care.

Relevant existing indicators:

BTS National NIV audit, 2010 – 2013. [5]

National data sources:

BTS National NIV audit, 2010 – 2013. [5]

National Confidential Enquiry into Patient Outcome and Death. Inspiring Change. London: NCEPOD; 2017. [4]

Source references:

BTS/ICS Guidelines for the Ventilatory Management of Acute Hypercapnic Respiratory Failure in Adults (2016). [3]

Clinical Quality Indicators for Acute Medical Units (AMUs). The Society for Acute Medicine (2011). [14]

Other information:

Example TEP for acute NIV (to follow on publication)

List of appendices:

Appendix 1 – NIV service infrastructure checklist.

Appendix 2 – NIV service staff training checklist

Additional appendices will be provided on publication, to include:

- Sample escalation plan
- Sample NIV prescription/protocol

Bibliography:

1) BTS Guideline Production Manual 2016:
https://www.brit-thoracic.org.uk/guidelines-and-quality-standards/

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Appendix 1 – NIV service infrastructure checklist

Adapted from BTS/ICS Guidelines for the Ventilatory Management of Acute Hypercapnic Respiratory Failure in Adults (March 2016) and National Confidential Enquiry into Patient Outcome and Death – July 2017 – Inspiring Change – Acute Non-Invasive Ventilation

#	Specifications	Is it met? Y/N/Planned	Comments	Action required	Timescale	Person responsible
The purpose of this specification is to improve the quality of care provided to patients receiving acute non-invasive ventilation (NIV). Issues in relation to the timeliness, appropriateness, location, level of care and competency of staff treating patients with acute NIV have been highlighted.						
1	AREA: Acute NIV should only be used in clinical areas equipped with: a) Continuous pulse oximetry for all patients. b) Continuous ECG monitoring for all patients with a clinical indication (pulse rate > 120 bpm, dysrhythmia or possible cardiomyopathy). c) Point of care blood gas analyser within the NIV area.					
2	LEADERSHIP: There should be a clinical lead for the NIV service with time allocated in their job plan, a designated lead nurse and, where appropriate, a designated lead physiotherapist.					
3	STAFFING: 1:2 nursing care should be provided for all patients treated with acute NIV until NIV requirements reduce to nocturnal use only. The local operational policy should include a management / escalation plan for critically ill patients who require increased (1:1) nursing care.					
4	EQUIPMENT: All ventilators used to deliver acute NIV should be designed for this purpose. There should be sufficient quantity of masks and ventilators to meet the expected demand for NIV.					
5	SERVICE CAPACITY: Designated NIV area(s) should have sufficient capacity to meet the demand for acute NIV. If NIV starts in other areas, trained staff should remain with					

	the patient during delivery of NIV; the same monitoring should be provided and transfer to a designated NIV area should occur within 4 hours.					
6	GOVERNANCE: The NIV service should have: a) A locally developed NIV protocol (based on published best practice guides) uniformly applied across all areas. b) A process of regular audit (continuous rolling audit is recommended), including participation in national audits. c) A robust morbidity and mortality (M&M) process including regular M&M meetings (including rapid review of all inpatient deaths of patients treated with (or considered for) acute NIV).					

Appendix 2 – NIV service staff training checklist

Adapted from BTS/ICS Guidelines for the Ventilatory Management of Acute Hypercapnic Respiratory Failure in Adults (March 2016) and National Confidential Enquiry into Patient Outcome and Death – July 2017 – Inspiring Change – Acute Non-Invasive Ventilation

#	Specifications	Is it met? Y/N/Partially/Planned	Comments	Action required	Timescale	Person responsible
The purpose of this specification is to improve the quality of care provided to patients receiving acute non-invasive ventilation (NIV). Issues in relation to the timeliness, appropriateness, location, level of care and competency of staff treating patients with acute NIV have been highlighted.						
1	Provision of an NIV training programme for staff with responsibility to start or continue NIV.					
2	Training portfolios of nurses / physiotherapists / doctors / physiologists confirm that they have attended such training.					
3	Staffing arrangements such that new / untrained members of staff with any responsibility for the care of patients treated with NIV are directly supervised by a trained member of staff until NIV competence is achieved and documented.					
4	A rolling competency maintenance framework that is appropriate for their continued practice. This will differ according to role with the recommended approach as follows; 1) **Healthcare professionals with responsibility to make practical changes to NIV (e.g. setting up NIV, adjusting ventilator settings and mask):** • Annual review of competence, ideally observed by the trust lead for training.					

	2) **Healthcare professionals with responsibility for clinical decisions regarding NIV therapy:** • New staff (e.g. rotating ST3+ grade) should receive a review of the theory and evidence-base for NIV as part of their induction. • Existing staff (e.g. consultant with on-call responsibility for NIV) should review their competence annually via appraisal / mandatory training and should ensure attendance at an acute medical update that includes NIV within each revalidation cycle.					