Lessons learnt from the National Confidential Enquiry into Patient Outcome and Death: acute non-invasive ventilation

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The British Thoracic Society (BTS) first produced a guideline on acute non-invasive ventilation (NIV) in 2002.[1] Earlier studies had established a survival benefit and reduced hospital stay for selected patients with chronic obstructive pulmonary disease (COPD).[2 3] Patients with milder acute hypercapnic respiratory failure (AHRF) due to COPD (pH 7.30–7.35) could be treated in a ward setting. No benefit was found when ward-based NIV was used for patients with pH<7.30.[3] Initially, there was limited availability of NIV in clinical practice,[4] though new services developed as the evidence base grew. In 2004, the National Institute for Health and Clinical Excellence (NICE) recommended that NIV should be available in all hospitals admitting patients with COPD.[5] The 2002 BTS NIV guideline defined the indications for NIV, described the optimal delivery of NIV and set standards of care. It comprised 41 recommendations (2 at grade A). Key recommendations are shown in table 1.

The 2002 guideline also recommended regular audit of acute NIV services. National audits were emerging and a collaboration between the Royal College of Physicians of London (RCP) and BTS led to a series of national audits of acute hospital COPD care. The 2003 COPD audit showed that NIV was available in 89% of hospitals.[6] However, only 31% of patients who presented with AHRF received NIV.[7] An updated NIV guideline was produced in 2008, focused on the use of acute NIV to manage patients with AHRF due to COPD.[8] Its remit included patient selection, NIV set-up, monitoring and treatment escalation. It provided 28 recommendations (11 at grade A).

The 2008 COPD audit placed a greater emphasis on NIV outcomes and highlighted numerous concerns.[9] Some patients did not receive NIV despite meeting evidence-based criteria, whereas others did receive NIV when it was not indicated. There was a lack of sufficient trained staff, insufficient ventilators to provide NIV to all who needed it and fewer than half of patients with AHRF received NIV within 3 hours of presentation.

The BTS established a national acute NIV audit and provided its first report in 2010 with further annual audits until 2013.[10] While COPD was the indication for NIV for the majority of patients, BTS audits provided outcome data for all patients treated with NIV. All audit cycles raised important questions about the quality of NIV care and the organisation of NIV services in the UK. Data of particular concern from the 2013 audit (2693 patients, 148 UK hospitals) included;

1. Patient selection: Ward-based NIV is not recommended for patients with pneumonia. Despite this, consolidation was present in 40%; if present, mortality was higher (35% vs 22%).
2. Possible treatment delay: Median pre-NIV pH fell in successive audits, consistent with increasing physiological derangement at the time of starting NIV. Other factors such as age, frailty and diagnosis were unchanged.
3. Location of NIV treatment: Median pre-NIV pH was 7.24, yet 91% of patients were not treated in a high dependency unit/ICU environment. Mortality was highest for patients who started NIV in general medical wards (59%).
4. High mortality rates (34%) and low rates of intubation (3%) if NIV failed. Mortality rates increased, rather than improved, in successive audits.

To answer the questions raised by successive audits, the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) conducted a detailed review of clinical practice in all hospitals in the UK. Clinical coding data identified 9299 patients treated with NIV between 1st February and 31st March 2015, the same 2 months used for BTS audit.

While the NCEPOD study was in progress, the BTS and the Intensive Care Society (ICS) coproduced a new guideline in 2016.[11] This guideline covered a broader range of patients, including all causes of AHRF, not just COPD, and also a wider remit, including pre-NIV management and invasive ventilation. Its aim was to improve resourcing,

Key messages

What is the key question?
- What do guidelines say about how to deliver non-invasive ventilation (NIV) and how are they applied in clinical practice?

What is the bottom line?
- Guidelines provide consistent recommendations but NIV is delivered inconsistently.

Why read on?
- Understanding how practice can be improved will help to deliver improved care and outcomes for these high-risk patients.

Table 1 Comparison of national and international guidelines relating to treatment with acute NIV

	NIV in acute respiratory failure[1]	COPD: NIV with biphasic positive airways pressure in the management of patients with acute type 2 respiratory failure[8]	BTS/ICS Guidelines for the ventilatory management of acute hypercapnic respiratory failure in adults[11]	Official ERS/ATS clinical practice guidelines: NIV for acute respiratory failure[12]
Publication date	2002	2008	2016	2017
Organisation(s)	BTS	RCP, BTS, ICS	BTS, ICS	ERS, ATS
Remit	Use of NIV and CPAP to treat adult patients with ARF.	Use of NIV in emergency and ward areas of acute hospitals to treat patients with AHRF due to COPD.	Assessment and management of adult patients with AHRF, including use of NIV and invasive ventilation.	Use of NIV to treat adults with acute respiratory failure. In this document, NIV refers to bilevel NIV and CPAP.
Methodology	SIGN	SIGN	SIGN	Assessment, Development and Evaluation (GRADE)
GRADE A OR strong indications for NIV	Acute exacerbation of COPD (AECOPD) pH<7.35 despite controlled O_2.	AECOPD with pH<7.35, $PaCO_2$>6 kPa, despite maximal medical therapy and controlled O_2 for no more than 1 hour.	AECOPD with pH<7.35 and $PaCO_2$>6.5 kPa that persists or develops despite optimal medical therapy.	AECOPD with pH≤7.35. NIV or CPAP for patients with (ARF) due to cardiogenic pulmonary oedema.
Location of NIV care (grade)	HDU/ICU for patients with pH<7.30 or failure to improve after 1–2 hours of NIV on a respiratory ward. (C)	HDU/ICU for patients with<7.26 unless NIV is ceiling of therapy. (A)	A clinical environment with enhanced nursing and monitoring facilities beyond those of a general medical ward. (C)	No recommendation.
Staff competency (GRADE)	Training appropriate to baseline knowledge and role. (D)	Staff appropriately trained and experienced. (B)	Regular staff educational updates and training module for new staff.	No recommendation.
Staffing levels (GRADE)	No recommendation.	Minimum staffing ratio of 1 nurse to 2 NIV patients for at least the first 24 hours of NIV. (C)	Enhanced nursing and monitoring facilities beyond those of a general medical ward. (C) box 3 in guideline: Essential requirements for NIV; 1 nurse to 2 NIV cases (especially during the first 24 hours of treatment).	No recommendation.
Timing	No recommendation.	Consider NIV for all patients with AECOPD and persisting AHRF (<7.35 and $PaCO_2$>6 kPa) despite maximal medical therapy and controlled O_2 for no more than 1 hour.	No recommendation.	No recommendation.
Physiological monitoring (GRADE)	Respiratory rate. (D) Heart rate. (D) Continuous SaO_2 for first 24 hours. (C)	Respiratory rate. (C) Heart rate. (C) Continuous SaO_2 and ECG for first 12 hours. (B)	No recommendation, though Good Practice Points (GCP) note; Respiratory rate>25 is a red flag. Continuous SaO_2 advised. ECG monitoring advised if pulse rate>120 bpm, dysrhythmia or possible cardiomyopathy.	No recommendation, though supplementary text supports continuous SaO_2 and frequent assessment of respiratory and heart rate.
Blood gas monitoring (GRADE)	As clinically indicated, plus routinely at 1–2 hours and after 4–6 hours of NIV. (B)	Minimum 1, 4 and 12 hours after NIV. (A)	No recommendation, though a GCP supports intermittent measurement of $PaCO_2$ and pH.	No recommendation. Supplementary text supports routine sampling. though timings differ (text=1–2 hours, table=30–60 min)
Documentation of treatment plan (GRADE)	Decision on tracheal intubation before starting NIV. Verified with senior medical staff as soon as possible and documented in the case notes. (D)	Plan in the event of NIV failure should be made at the outset. (C)	Initial care plans should include robust escalation arrangements. (C) Use of NIV may allow time to establish patient preference with regard to escalation to IMV. (D)	No recommendation.
Escalation (GRADE)	If no improvement in $PaCO_2$ and pH after 4–6 hours, NIV should be discontinued and IMV considered. (B)	A decision on IMV should normally be made within 4 hours of starting NIV (in the event of failure to improve). (A)	IMV should be considered if there is persistent or deteriorating acidosis despite attempts to optimise delivery of NIV. (A)	No recommendation.

AECOPD, acute exacerbation of COPD; AHRF, acute hypercapnic respiratory failure; ARF, acute respiratory failure; ATS, American Thoracic Society; BTS, British Thoracic Society; COPD, chronic obstructive pulmonary disease; CPAP, continuous positive airway pressure; ERS, European Respiratory Society; GCP, Good Practice Point; HDU, high dependency unit; ICS, Intensive Care Society; ICU, intensive care unit; IMV, invasive mechanical ventilation; NIV, non-invasive ventilation; RCP, Royal College of Physicians of London; SIGN, Scottish Intercollegiate Guideline Network.

training, outcomes and patient experience for all adults who develop AHRF. It recognised a need for a more coordinated hospital-wide approach to patient care. There were 82 recommendations (6 at grade A). The guideline group set out the appropriate care environment for the delivery of NIV and seven essential requirements for an NIV service. Key recommendations from all three guidelines are compared in table 1.

The European Respiratory Society and American Thoracic Society also published NIV guidelines in 2017.[12] Recommendations focused on 13 clinical indications rather than delivery of care, weighted according to the strength of evidence. There were only two strong recommendations, with eight conditional recommendations. Outside of the GRADE methodology, the authors also provided a supplementary technical summary to describe practical aspects of NIV.

NCEPOD's study of NIV, 'Inspiring Change,' was published in 2017.[13] It identified a number of key areas where the organisation of care and clinical application of NIV can be improved and made a total of 21 recommendations. A sample of 432 cases was analysed using a clinician questionnaire completed by the consultant responsible for the patient. Case notes for 353 cases were reviewed in detail by a multidisciplinary group of clinicians. Of the patients studied, the primary diagnosis on admission was COPD in just under 70% of cases. The majority (53.1%) had two or more comorbid conditions and 56.8% were at least moderately frail, needing help with outdoor activity, housekeeping or climbing stairs. Demographic details were similar to BTS audit data as was the mortality rate (34.6%).

The 2008 COPD audit had demonstrated a delay in starting NIV for 51% of patients[9] and the progressive fall in pre-NIV

pH described in the BTS audit[10] raised the possibility that treatment delay remained an issue. NCEPOD confirmed that there was delay in starting treatment in 96/350 (27.4%) cases. In 41 of these cases, the delay was due to a failure to recognise that NIV treatment was needed. There were also 28 cases where the delay was caused by a need to transfer the patient to another clinical area to start treatment. The NCEPOD review recommended that NIV should be started within an hour of the blood gas that identified the need for it.[13]

For individual organisations, local arrangements for NIV delivery should be set down in an operational policy. NCEPOD recommended that each local policy should set out agreed arrangements for the delivery of the NIV service. This will include the clinical areas, equipment, staffing and staff competencies required. The 2008 NIV guideline recommended a staffing ratio of one nurse to two NIV patients during the first 24 hours of treatment.[8] In their 2009 document, 'Levels of Critical Care for Adult Patients', the ICS reiterated level 2 as the appropriate environment to deliver treatment with NIV.[14] However, the NCEPOD study showed that only 79/162 (48.8%) of UK hospitals used a defined ratio of nurses to patients. The recommended staffing ratio was achieved in 53 hospitals, demonstrating that it was possible to organise services in line with this guidance.

The NCEPOD review also found that in 70/154 (45.4%) hospitals, staff without a defined competency directly supervised patients on NIV. NIV was started by very junior staff in 59/382 (15.4%) of cases and in 58/300 (19.3%) cases, the patient was not reviewed on a daily basis while on NIV. Ventilator management was rated as inappropriate in 42.4% of cases. NCEPOD recommended that all patients treated with NIV must be discussed with a specialist competent in the management of NIV at the time treatment is started or at the earliest opportunity afterwards. Consultant specialist review to plan ongoing treatment should take place within a maximum of 14 hours.

BTS audits show that NIV fails to improve respiratory acidaemia in approximately a third of patients.[10] Setting a treatment escalation plan prior to starting NIV is recommended in guidelines, alongside early review to assess treatment response (table 1). In the NCEPOD review, there were signs of deterioration (rising respiratory rate, falling level of consciousness, worsening acidosis or agitation) in 145/345 (42%) cases. A referral to critical care was made in 156/328 (47.6%) cases. However, a treatment escalation plan was not made in 128/352 (36.4%) of cases reviewed. When an escalation plan was made later in the admission (in 302/432; 69.9%), a plan about suitability for invasive ventilation was still not made in 51/302 (16.9%) cases. NCEPOD has reinforced the guideline recommendation about escalation planning and has specified elements of practice that should be included in this process.[13]

Oxygen should be prescribed to a target oxygen saturation range for all hospital patients at the time of admission,[15] with an 88%–92% target for all patients at risk of AHRF.[11 15] NCEPOD found that 418/432 (96.8%) were receiving oxygen at the start of NIV. The method of oxygen delivery was recorded for only 158 patients, and controlled oxygen via Venturi mask was used for 27 (17.1%). Only 28.6% of patients achieved target oxygen saturations of 88%–92%. Oxygen toxicity contributed to hypercapnia in 26.9% of peer-reviewed cases, a worsening trend in comparison with BTS audit data.[10] Therefore, NCEPOD's review shows that oxygen misadministration prior to NIV remains problematic. The oxygen delivery device, the concentration of oxygen and the target saturation should all be documented in the patient record.

Table 2 The six statements of the BTS acute NIV quality standard[18]

1	Acute NIV should be offered to all patients who meet evidence-based criteria. Hospitals must ensure there is adequate capacity to provide NIV to all eligible patients.
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.
3	Acute NIV should only be carried out in specified clinical areas designated for the delivery of acute NIV.
4	Patients who meet evidence-based criteria for acute NIV should start NIV within 60 min of the blood gas result associated with the clinical decision to provide NIV and within 120 min of hospital arrival for patients who present acutely.
5	All patients should have a documented escalation plan before starting treatment with acute NIV. Clinical progress should be reviewed by a healthcare professional with appropriate training and competence within 4 hours of starting NIV and by a consultant with training and competence in acute NIV within 14 hours of starting acute NIV.
6	All patients treated with acute NIV should have blood gas analysis performed within 2 hours of starting acute NIV. Failure of these blood gas measurements to improve should trigger specialist healthcare professional review within 30 min.

BTS, British Thoracic Society; NIV, non-invasive ventilation.

Resolution of acidaemia and improvement of CO_2 are markers of improved ventilation and therefore response to treatment. Guidelines recommend blood gas analysis to assess response to ventilation, though audit data[10] and NCEPOD[13] confirm important omissions. NCEPOD found 'room for improvement' in blood gas sampling; in 107/331 (32.3%) cases, this was considered to be done too infrequently. Guidelines for NIV have also previously made specific recommendations about physiological monitoring during NIV treatment.[8] The most recent BTS guideline does not make specific recommendations,[11] although a respiratory rate of 25 or more is used as a flag to identify patients at increased risk. Use of the national early warning score is now recommended for use in all hospital patients to assess illness severity and identify at risk patients.[16] In the NCEPOD review, 128/254 (50.4%) of patients had a respiratory rate of 25 or above at the start of NIV. Patients who died had, on average a higher respiratory rate and higher heart rate than patients who survived throughout the first 4 hours of NIV treatment. Both a heart rate of 100 or more and a respiratory rate of 26 or more at the start of the NIV episode were associated with an increased risk of death (mortality 39.3% vs 24.8% for heart rate; 37.5% vs 23.1% for respiratory rate). In 104/311 (33.4%) cases reviewed, the reviewers found that vital signs were not monitored with the appropriate frequency. Alongside blood gas analysis, vital signs monitoring is therefore a key part of assessing severity of illness and risk of death in patients treated with NIV. NCEPOD recommended vital signs monitoring for patients on NIV treatment at least hourly until the respiratory acidaemia has resolved.

Following successful acute NIV, a structured plan for future treatment should be discussed with the patient. This should include future use of acute NIV and consideration of long-term overnight ventilation support at home, especially in light of the HOT-HMV trial, which showed that the addition of home NIV to oxygen therapy can reduce the risk of hospital readmission in patients with COPD with persisting hypercapnia after discharge.[17] Careful follow-up is essential. However, NCEPOD's review found that no documented decision was made about future use of NIV in 91.7% of the reviewed cases. Follow-up arrangements, if documented, were not made for 35.7% of

patients. Where follow-up was arranged, it did not take place in 34.5%. These are high-risk patients; almost one in six (49/270; 18.1%) were readmitted within 30 days of discharge. Prior BTS audit data show that persisting hypercapnia is common; where data were available, discharge $PaCO_2$ was >7 kPa for 50.8% and was >8 kPa for 26.1% of patients with COPD. In contrast, NCEPOD showed that only 7.2% of patients were discharged on home NIV.

The BTS has recently produced an NIV quality standard[18] drawn from the evidence and recommendations in the 2016 BTS Guideline and informed by the 2017 NCEPOD study and previous BTS audits. Its purpose is to provide a set of specific, concise statements that act as markers of high-quality, cost-effective patient care, together with measurable markers of good practice. The six statements of the quality standard (table 2) are endorsed by the RCP, the Royal College of Anaesthetists, the Royal College of Emergency Medicine, the Association of Chartered Physiotherapists in Respiratory Care, the Society for Acute Medicine and the ICS.

It is vital that organisations monitor performance against such standards locally to ensure the quality of NIV provision improves. However, the NCEPOD review found that only 74/162 (45.7%) hospitals reported undertaking annual audit of their service and only 39/165 (23.6%) hospitals routinely collected data on the number of NIV episodes they provided. There were 65 (39.4%) hospitals that reported having more patients requiring NIV than machines available during the year of the study and 44/154 (28.6%) had reported a serious incident relating to NIV in 2015.

In summary, UK and international guidelines provide comprehensive and consistent recommendations to support safe, effective use of acute NIV. However, successive national audits have demonstrated significant shortcomings in the delivery of care. The NCEPOD review has provided a detailed assessment of clinical practice. Some services are able to meet guideline recommendations and achieve good outcomes in a ward-based setting. However, many do not comply with these recommendations and many patients receive a poor standard of care. National audits in other areas of medicine (such as stroke or myocardial infarction) reveal falling mortality rates. The key to their success has been the reorganisation of services. Redesign of NIV services is now needed both to comply with guideline recommendations and to improve outcomes.[19] The NHS constitution states that patients 'have the right to expect NHS bodies to monitor, and make efforts to improve continuously, the quality of healthcare they commission or provide'.[20] Organisations that provide acute NIV must start by measuring the performance of their service and identify areas for improvement. Healthcare commissioners should also take a lead by monitoring the quality of acute NIV provided to their patients.

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REFERENCES

1 British Thoracic Society Standards of Care Committee. Non-invasive ventilation in acute respiratory failure. *Thorax* 2002;57:192–211.
2 Bott J, Carroll MP, Conway JH, *et al*. Randomised controlled trial of nasal ventilation in acute ventilatory failure due to chronic obstructive airways disease. *Lancet* 1993;341:1555–7.
3 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;355:1931–5.
4 Roberts CM, Ryland I, Lowe D, *et al*. Audit of acute admissions of COPD: standards of care and management in the hospital setting. *Eur Respir J* 2001;17:343–9.
5 National Collaborating Centre for Chronic Conditions. Chronic obstructive pulmonary disease. National clinical guideline on management of chronic obstructive pulmonary disease in adults in primary and secondary care. *Thorax* 2004;59(Suppl 1):1-232.
6 Price LC, Lowe D, Hosker HS, *et al*. UK National COPD Audit 2003: Impact of hospital resources and organisation of care on patient outcome following admission for acute COPD exacerbation. *Thorax* 2006;61:837–42.
7 Kaul S, Pearson M, Coutts I, *et al*. Non-invasive ventilation (NIV) in the clinical management of acute COPD in 233 UK hospitals: results from the RCP/BTS 2003 National COPD Audit. *COPD* 2009;6:171–6.
8 Royal College of Physicians, British Thoracic Society, Intensive Care Society. *Chronic obstructive pulmonary disease: non-invasive ventilation with bi-phasic positive airways pressure in the management of patients with acute type 2 respiratory failure*. London: RCP, 2008. Concise Guidance to Good Practice series, No 11.
9 Roberts CM, Stone RA, Buckingham RJ, *et al*. Acidosis, non-invasive ventilation and mortality in hospitalised COPD exacerbations. *Thorax* 2011;66:43–8.
10 British Thoracic Society. BTS National NIV audit (2010-2013). https://www.brit-thoracic.org.uk/document-library/audit-and-ualityimprovement/audit-reports/bts-adult-niv-audit-report-2013/.
11 Davidson AC, Banham S, Elliott M, *et al*. BTS/ICS guideline for the ventilatory management of acute hypercapnic respiratory failure in adults. *Thorax* 2016;71:ii1–35.
12 Rochwerg B, Brochard L, Elliott MW, *et al*. Official ERS/ATS clinical practice guidelines: noninvasive ventilation for acute respiratory failure. *Eur Respir J* 2017;50:1602426.
13 National Confidential Enquiry into Patient Outcome and Death. *Inspiring Change*. London: NCEPOD, 2017.
14 Intensive Care Society. *Levels of critical care for adult patients*. London: Intensive Care Society, 2009.
15 O'Driscoll BR, Howard LS, Earis J, *et al*. British Thoracic Society Emergency Oxygen Guideline GroupBTS Emergency Oxygen Guideline Development Group. BTS guideline for oxygen use in adults in healthcare and emergency settings. *Thorax* 2017;72:ii1–90.
16 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..
17 Murphy PB, Rehal S, Arbane G, *et al*. Effect of Home Noninvasive Ventilation With Oxygen Therapy vs Oxygen Therapy Alone on Hospital Readmission or Death After an Acute COPD Exacerbation: A Randomized Clinical Trial. *JAMA* 2017;317:2177–86.
18 Davies M, Allen M, Bentley A, *et al*. British Thoracic Society Quality Standards for acute non-invasive ventilation in adults. *BMJ Open Respir Res* 2018;5:e000283.
19 The Lancet Respiratory Medicine. Raising standards in the delivery of acute NIV. *Lancet Respir Med* 2017;5.
20 NHS. The NHS Constitution for England. 2015 https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england.