

CONCISE GUIDANCE TO GOOD PRACTICE

A series of evidence-based guidelines for clinical management

NUMBER 11

Non-invasive ventilation in chronic obstructive pulmonary disease: management of acute type 2 respiratory failure

NATIONAL GUIDELINES

October 2008



Clinical Standards Department

The purpose of the Clinical Standards Department of the Royal College of Physicians is to improve patient care and healthcare provision by setting clinical standards and monitoring their use. We have expertise in the development of evidence-based guidelines and the organisation and reporting of multicentre comparative performance data. The department has three core strategic objectives: to **define** standards around the clinical work of physicians, to **measure** and evaluate the implementation of standards and its impact on patient care; and to effectively **implement** these standards.

Our programme involves collaboration with specialist societies, patient groups and national bodies including the National Institute for Health and Clinical Excellence (NICE), the Healthcare Commission and the Health Foundation.

Concise Guidance to Good Practice series

The concise guidelines in this series are intended to inform those aspects of physicians' clinical practice which may be outside their own specialist area. In many instances the guidance will also be useful for other clinicians including GPs and other healthcare professionals.

The guidelines are designed to allow clinicians to make rapid, informed decisions based wherever possible on synthesis of the best available evidence and expert consensus gathered from practising clinicians and service users. A key feature of the series is to provide both recommendations for best practice, and where possible practical tools with which to implement it.

Series Editors: Lynne Turner-Stokes FRCP and Bernard Higgins FRCP

Guideline Development Group

This guidance was prepared on behalf of the multidisciplinary Guideline Development Group convened by the Clinical Standards Department of the Royal College of Physicians (RCP) and the British Thoracic Society (BTS) in association with the Intensive Care Society (ICS).

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Acknowledgement

Julia Bott provided invaluable input into this document during the latter stages of development.

Citation: 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*. Concise Guidance to Good Practice series, No 11. London: RCP, 2008.

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Registered Charity No 210508

ISBN 978-1-86016-344-9

Review date: 2012

Designed and typeset by the Publications Unit
of the Royal College of Physicians

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Non-invasive ventilation (NIV) in the management of acute type 2 respiratory failure in patients with chronic obstructive pulmonary disease (COPD) represents one of the major technical advances in respiratory care over the last decade. The National Institute for Health and Clinical Excellence (NICE) recommends that NIV be available in all hospitals admitting patients with COPD.¹ This has led to a rapid expansion in the provision of NIV services, with over 90% of UK admitting hospitals offering this intervention. The UK national audit of acute hospital COPD care in 2003, however, suggested that treatment was often applied to patients outside the existing British Thoracic Society (BTS) inclusion criteria.^{2,3} This document updates the 2002 BTS guidance and provides a specific focus on the use of NIV in COPD patients with acute type 2 respiratory failure. Although a variety of ventilator units are available, most centres now use bi-level positive airways pressure (BiPAP) units and this guideline refers specifically to this form of ventilatory support, although many of the principles encompassed are applicable to other forms of NIV. The guideline has been produced for the clinician caring for COPD patients in the emergency and ward areas of acute hospitals. Guideline development was in accordance with the Appraisal of Guidelines for Research and Evaluation (AGREE) principles and is summarised in [Appendix 1](#). An extended version of this guideline, encompassing service provision, is available on the [BTS website](#).

Clinical context

Non-invasive ventilation (NIV), within both the intensive care unit (ICU) and the ward environment, has been shown in randomised controlled trials (RCTs) and systematic reviews^{5–14} to reduce intubation rate and mortality in COPD patients with decompensated respiratory acidosis (pH <7.35 and PaCO₂ >6 kPa) following immediate medical therapy. NIV should therefore be considered within the first 60 minutes of hospital arrival in all patients with an acute exacerbation of COPD in whom a respiratory acidosis persists despite maximum standard medical treatment, which includes:

- controlled oxygen to maintain SaO₂ 88–92%
- nebulised salbutamol 2.5–5 mg
- nebulised ipratropium 500 µg
- prednisolone 30 mg
- antibiotic agent (when indicated).

Recommended inclusion and exclusion criteria for potential NIV are shown in Table 1.

A clearly documented treatment plan for NIV, including how potential failure will be dealt with and whether escalation to intubation and mechanical ventilation is indicated, should be recorded in the case notes at the outset of treatment. Whenever possible, the patient and carers should be involved in these discussions. Once started, patient comfort, breathing synchrony and enhanced compliance are key factors in determining outcome. Low starting pressures increase patient compliance, but should be quickly adjusted upwards to achieve therapeutic effect. If effective, treatment will usually be required until the acute cause has resolved, commonly within about three days.

Table 1. Clinical inclusion and exclusion criteria for NIV. 9,10,12

Inclusion criteria	Exclusion criteria
<p>Primary diagnosis of COPD exacerbation (known diagnosis or history and examination consistent with diagnosis)</p> <p>*Able to protect airway</p> <p>*Conscious and cooperative</p> <p>Potential for recovery to quality of life acceptable to the patient</p> <p>Patient's wishes considered</p> <p> </p> <p>*Consider NIV if unconscious and endo-tracheal intubation deemed inappropriate or NIV to be provided in a critical care setting. There is evidence¹⁵ to support the use of NIV in patients who are comatose secondary to COPD-induced hypercapnea.</p>	<p>Life-threatening hypoxaemia</p> <p>Severe co-morbidity</p> <p>Confusion/agitation/severe cognitive impairment</p> <p>Facial burns/trauma/recent facial or upper airway surgery</p> <p>Vomiting</p> <p>Fixed upper airway obstruction</p> <p>Undrained pneumothorax</p> <p>Upper gastrointestinal surgery</p> <p>Inability to protect the airway</p> <p>Copious respiratory secretions</p> <p>Haemodynamically unstable requiring inotropes/pressors (unless in a critical care unit)</p> <p>Patient moribund</p> <p>Bowel obstruction</p> <p>NIV is not the treatment of choice for patients whose primary diagnosis is heart failure or pneumonia but may be used in COPD patients with these complications if escalation to intubation and ventilation is deemed inappropriate.</p>

1 Documentation

1.1 An acute NIV service should have a local protocol stating: A

- criteria for selection and treatment of patients ^{9,16–18}
- the local setting in which they should be treated.

More sick or complex patients, eg with a pH <7.26, should be managed with a low threshold for intubation, unless NIV is deemed to be the ceiling of treatment, and be admitted to a high dependency unit (HDU) or ICU depending upon local circumstances.^{2,9}

1.2 Documentation for each patient should include: C

- a written prescription for the use of acute NIV
- a record of compliance including breathing synchrony with NIV treatment documented including hours of use, times on NIV
- a documented plan which addresses:
 - how potential failure of NIV will be dealt with
 - whether escalation of care is indicated
 - whether NIV is the ceiling of treatment
 - whether the patient is for resuscitation or specific palliative care measures.

Patient information on the use of NIV should be available for all COPD patients treated in hospital.

2 Patient selection

2.1 NIV should be considered in all patients with an acute exacerbation of COPD in whom a respiratory acidosis (pH <7.35 PaCO₂ >6 kPa), persists despite immediate maximum standard medical treatment on controlled oxygen therapy for no more than 1 hour.^{12,13} A

2.2 Patients should be stratified into five groups based on: A

- their pre-morbid state
- the severity of the physiological disturbance
- the reversibility of the acute illness
- the presence of relative contraindications (see Table 1), *and*
- where possible, the patient's wishes.

2.3 The stratification should be recorded in the medical notes: C

- (1) requiring immediate intubation and ventilation
- (2) suitable for NIV and suitable for escalation to intensive care treatment/ intubation and ventilation if required
- (3) suitable for NIV but not suitable for escalation to intensive care treatment/ intubation and ventilation
- (4) not suitable for NIV but for full active medical management
- (5) palliative care agreed as most appropriate management.

3 Set-up

3.1 The decision to commence NIV should be made by a doctor of specialty training (ST) level 2 or above who is competent to do so. A trained and competent healthcare professional should initiate NIV.¹⁶ C

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<i>Recommendation</i>	<i>Grade of evidence*</i>
<p>The patient should be in a sitting or semi-recumbent position in bed and the following are recommended:</p>	
<ul style="list-style-type: none">• A full-face mask should be used for the first 24 hours, followed by switching to a nasal mask if preferred by the patient.	C
<ul style="list-style-type: none">• An initial inspiratory positive airway pressure (IPAP) of 10 cm H₂O and expiratory positive airway pressure (EPAP) of 4–5 cm H₂O should be used. (These settings are well tolerated by most patients.⁹)	A
<ul style="list-style-type: none">• IPAP should be increased by 2–5 cm increments at a rate of approximately 5 cm H₂O every 10 minutes, with a usual pressure target of 20 cm H₂O or until a therapeutic response is achieved or patient tolerability has been reached.⁹	A
<ul style="list-style-type: none">• Oxygen, when required, should be entrained into the circuit and the flow adjusted to achieve the target saturation, usually 88–92%.¹⁹	B
<ul style="list-style-type: none">• Bronchodilators, although preferably administered off NIV, should as necessary be entrained between the expiration port and face mask. (Delivery of both oxygen and nebulised solutions is affected by NIV pressure settings.^{20–22})	A
<ul style="list-style-type: none">• If a nasogastric tube is in place, a fine bore tube is preferred to minimise mask leakage.	C
<h4>4. Monitoring</h4>	
<p>4.1 Monitoring should include a mixture of physiological measures and clinical parameters.^{23–27}</p>	B
<p>These parameters should be used to assist in formulating a management plan and within the first 4 hours of NIV assist in the decision as to the need to escalate to intubation.^{4,9}</p>	A
<p>4.2 Staff involved in the care and monitoring of NIV patients should be appropriately trained and experienced.^{16,28,29}</p>	B
<p>4.3 The following should be recorded and be used to formulate an iterative management plan:</p>	C
<ul style="list-style-type: none">• Baseline observations:<ul style="list-style-type: none">– arterial blood gas (ABG)– respiratory rate– heart rate• Continuous pulse oximetry and electrocardiogram (ECG) recording during the first 12 hours²³• Repeat ABGs:<ul style="list-style-type: none">– after 1 hour of NIV therapy and 1 hour after every subsequent change in settings– after 4 hours, or earlier in patients who are not improving clinically• Frequent clinical monitoring of acutely ill patients:<ul style="list-style-type: none">– every 15 minutes in the first hour– every 30 minutes in the 1- to 4-hour period– hourly in the 4- to 12-hour period• Observations including:<ul style="list-style-type: none">– respiratory rate, heart rate– level of consciousness, patient comfort– chest wall movement, ventilator synchrony, accessory muscle use.	

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<i>Recommendation</i>	<i>Grade of evidence*</i>
4.4 Patient comfort and enhanced compliance are key factors in determining outcome: <ul style="list-style-type: none">• Synchrony of ventilation should be checked frequently.• A clinical assessment of mask fit to include skin condition and degree of leak (particularly on the corneas) should be performed at the same time.^{9,27}	A
5 Escalation	
5.1 A management plan in the event of NIV failure should be made at the outset: <ul style="list-style-type: none">• The appropriateness for escalation to invasive mechanical ventilation should be assessed and recorded at the initiation of NIV.• When there is uncertainty or the patient is to be denied invasive mechanical ventilation then this should be discussed with the responsible clinical consultant.• If escalation is deemed appropriate this should be discussed with the ICU team.• Treatment options should also where possible be discussed with the patient unless s/he does not have capacity to do so.³⁰	C
5.2 A decision to intubate and proceed to invasive mechanical ventilation should normally be made within 4 hours of starting NIV or sooner. Improvements in respiratory rate, heart rate and arterial blood gas parameters are usually apparent within this time. ^{9,16}	A
5.3 Intubation rather than further NIV should be considered in patients suffering 'late failure' (defined as failure after 48 hours of non-invasive ventilation). ³¹	B
5.4 Decisions not to proceed to invasive mechanical ventilation should be taken by a consultant.	C
6 Duration of treatment	
6.1 Patients who benefit from NIV during the first 4 hours of treatment should receive NIV for as long as possible (a minimum of 6 hours) during the first 24 hours. ^{4-6,32,33}	A
6.2 Treatment should last until the acute cause has resolved, commonly after about 3 days.	C
6.3 In patients in whom NIV is successful (pH \geq 7.35 achieved, resolution of underlying cause and symptoms, respiratory rate normalised) following the first 24 hours or longer, it is appropriate to start a weaning plan: <ul style="list-style-type: none">• gradual reduction of the duration of NIV should be determined by clinical improvement• the use of a proforma to chart physiological indices has been shown to improve successful weaning from NIV.³³	C
7 Weaning	
7.1 Initially weaning should be during the day with extended periods off the ventilator for meals, physiotherapy, nebulised therapy etc. After successfully weaning during the day, many patients will require an additional night on NIV.	C
7.2 The weaning strategy should be documented in the medical and nursing records. The following is recommended: ^{7,17}	C

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<i>Recommendation</i>	<i>Grade of evidence*</i>
<ul style="list-style-type: none">• continue NIV for 16 hours on day 2• continue NIV for 12 hours on day 3 including 6–8 hours overnight use• discontinue NIV on day 4, unless continuation is clinically indicated. <p>Note that some patients may:</p> <ul style="list-style-type: none">• show at an earlier stage that they no longer require NIV and self-wean• improve rapidly, prompting a clinical decision to wean early• require long-term nocturnal support, indicated following assessment by the respiratory team.	A
8 Palliation	
<p>8.1 Palliation of symptoms is appropriate in some patients, where standard medical treatment and NIV fails and a decision has been made and documented not to escalate to intubation and mechanical ventilation, or where a patient chooses not to have NIV or other interventionist treatment:³⁴</p> <ul style="list-style-type: none">• If the patient gains symptom relief, continued NIV may be appropriate for palliation of breathlessness, but normally would be withdrawn.• Opiates and benzodiazepines can be used to treat breathlessness in this situation.• The palliative care team should be involved and a suitable care pathway followed after discussion with the patient and family.	C

* For explanation of grades of evidence, see [Appendix 2](#).

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Appendix 1. Guideline development process

These guidelines have been developed in accordance with the principles laid down by the Appraisal of Guidelines for Research and Evaluation (AGREE).

Scope and purpose

Overall objective of the guidelines	The objective of the Guideline Development Group was to partially update the British Thoracic Society (BTS) guideline, <i>Non-invasive ventilation in acute respiratory failure</i> , focusing on the use of non-invasive ventilation (NIV) in acute respiratory failure secondary to COPD.
The patient group covered	Individuals requiring non-invasive ventilation in acute respiratory failure secondary to COPD.
Target audience	Respiratory physicians, emergency medicine physicians, nurses with a special interest, physiotherapists with a special interest, junior medical staff, intensive care physicians/intensivists, general physicians, acute medicine physicians.
Clinical areas covered	<ul style="list-style-type: none">• selecting the patients suitable for NIV• set up of NIV• monitoring of patients managed with NIV• escalation.

Stakeholder involvement

The Guideline Development Group	A multidisciplinary group comprising: professionals, consultants in respiratory medicine, intensive care. User representation through the British Lung Foundation.
Funding	This guideline was commissioned and edited without external funding being sought.
Conflicts of interest	No external funding has been sought or obtained. All authors and group members have declared, and provided details, on any actual or potential conflicts of interest.

Rigour of development

Evidence gathering	Evidence for these guidelines was provided by review of Cochrane Library, Medline, Embase, conference proceedings and other guidelines up to 1988. Articles not published in English were excluded. Much of the advice is based on expert opinion and practice because of a lack of other evidence.
Piloting and peer review	The final draft was widely circulated to a multidisciplinary panel of all relevant parties and their comments incorporated.

Implementation

Methods of implementation	Free access on the Royal College of Physicians (RCP) website.
Barriers to implementation	Potential barriers to the successful implementation of these guidelines may be: failure of clinician acceptance of guidelines, or service resource limitations.
Plan for review	Review is planned for 4 years' time.

Appendix 2. Grading system from the Scottish Intercollegiate Guidelines Network (SIGN) methodology

Level of evidence	Type of evidence	Grade of recommendation
Ia	Meta-analysis of randomised controlled trials (RCTs)	A
Ib	At least one RCT	A
IIa	At least one well-designed controlled study, but without randomisation	B
IIb	At least one well-designed quasi-experimental design	B
III	At least one non-experimental descriptive study (eg comparative, correlation or case study)	B
IV	Expert committee reports, opinions and/or experience of respected authorities	B

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1. The use of botulinum toxin (BTX) in the management of spasticity in adults 2002
2. Infective endocarditis 2004 (available on web only)
3. HIV testing for patients attending general medical services 2005
4. Use of antidepressant medication in adults undergoing recovery and rehabilitation following acquired brain injury 2005
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