Home Noninvasive Ventilation

What Does the Anesthesiologist Need to Know?

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ABSTRACT

Treatment of chronic respiratory failure with noninvasive ventilation (NIV) is standard pediatric practice, and NIV systems are commonly used in the home setting. Although practice guidelines on the perioperative management of children supported with home NIV systems have yet to be published, increasingly these patients are referred for consultation regarding perioperative management. Just as knowledge of pharmacology underlies the safe prescription of medication, so too knowledge of biomedical design is necessary for the safe prescription of NIV therapy. The medical device design requirements developed by the Organization for International Standardization provide a framework to rationalize the safe prescription of NIV for hospitalized patients supported at home with NIV systems. This review article provides an overview of the indications for home NIV therapy, an overview of the medical devices currently available to deliver it, and a specific discussion of the management conundrums confronting anesthesiologists.

NONINVASIVE ventilation (NIV) refers to a technique of augmenting alveolar ventilation without the requirement for an invasive artificial airway. The use of NIV in the home was introduced in the 1980s for the long-term treatment of sleep apnea, and has more recently been used for the management of chronic hypercapnic respiratory failure. Management of acute respiratory failure may also include NIV, both to avoid invasive ventilation and to facilitate weaning from mechanical ventilation. Interested readers are referred to a recent review in Lancet. This review focuses on the use of NIV in the home for the management of chronic stable respiratory failure and/or obstructive sleep apnea.

Children with Duchenne muscular dystrophy were among the first patients to be managed with domiciliary NIV therapy. Children currently represent 10% of patients managed in home ventilation programs. Children on home NIV therapy are now presenting to anesthesiologists for diagnostic and surgical procedures. There are substantial questions concerning the optimal management of these children: Should they be permitted the use of their own domiciliary NIV medical devices? Are they eligible for ambulatory surgical programs? With respect to their own NIV medical devices, the ECRI Institute (formerly Emergency Care Research Institute) has cautioned hospitals against the use of patientsupplied medical equipment. The answers to the above require a working understanding of the indications for home NIV therapy, the medical devices used to deliver it, and the impact of sedative and analgesic medications on NIV therapy. This review provides an overview of the indications for NIV therapy, an overview of the medical devices available to...
deliver NIV therapy, and a specific discussion of management conundrums facing anesthesiologists. The discussion focuses on children, because the use of NIV therapy in the pediatric patient exposes the limitations of NIV systems. However, these pediatric concerns may also be relevant to small adults and patients with poor respiratory muscle strength and reduced respiratory neural drive.

The technique of noninvasive ventilation has two unique features that distinguish it from invasive ventilation with an endotracheal tube. First, noninvasive ventilation employs a nonhermetic technique, and the mask interface is deliberately designed to leak. Second, whereas invasive ventilation bypasses the upper airway with an endotracheal tube, the noninvasive ventilation system incorporates the upper airway into the breathing pathway. Noninvasive ventilation modalities include continuous positive airway pressure (CPAP) and noninvasive positive airway pressure ventilation (NIPPV), both of which deliver a therapeutic positive airway pressure. NIPPV is also referred to by the acronym NPPV (noninvasive positive pressure ventilation) and BiPAP (bilevel positive airway pressure), and BiPAP® is also the name of a NIV medical device manufactured by Philips Respironics (Murrysville, PA).

**An Overview of the Indications for Domiciliary NIV Medical Indications for Home CPAP Therapy.** In 1981, Colin Sullivan introduced CPAP therapy as a modality to reverse the symptoms of obstructive sleep apnea (OSA). CPAP therapy is currently widely prescribed for the management of OSA in adults and in children with OSA refractory to adenotonsillectomy. During CPAP therapy, the positive airway pressure acts as a pneumatic splint for the pharyngeal airway. It also increases lung volume (i.e., functional residual capacity). Both actions act to decrease the collapsibility of the upper airway and thereby mitigate obstruction of the pharyngeal airway, offset auto-positive end-expiratory pressure, reduce the load on respiratory muscles, and decrease the work of breathing. In adult patients, CPAP levels of 5 and 10 cm H2O may increase tidal volume by 80 ml and 150 ml, respectively. CPAP therapy may also improve gas exchange. In patients with coexistent pulmonary disease and OSA, CPAP therapy may also improve lung function. In patients with coexistent heart failure and OSA, CPAP therapy may improve cardiac function.

Prescription of home CPAP therapy in children is reserved for those with OSA refractory to adenotonsillectomy. Initiation of CPAP therapy usually involves a CPAP titration study in a sleep laboratory. Once discharged home on CPAP devices, children are followed in outpatient clinics, and their management requires periodic review with overnight polysomnography. Preoperative consultation with the sleep physician or respiriologist is important.

**Medical Indications for Home NIPPV Therapy.** In chronic respiratory failure associated with neuromuscular disease and morbid obesity, respiratory muscle weakness may lead to hypoventilation during both sleep and wakefulness. Hallmarks of hypoventilation during wakefulness are a chronic compensated respiratory acidosis, i.e., daytime hypercapnia with an increased serum bicarbonate level, and a low oxygen saturation on room air during wakefulness. Management of chronic hypercapnic respiratory failure with domiciliary NIPPV in children with neuromuscular and chest wall disease is now standard practice.

NIPPV therapy aims to deliver a therapeutic pressure during inspiration — the inspiratory positive airway pressure (IPAP) — and hold a positive pressure on exhalation — the expiratory positive airway pressure (EPAP). Like CPAP therapy, bilevel airway pressure therapy aims to splint the pharyngeal airway and preserve lung volume. During inspiration, NIPPV therapy further augments airway pressure by increasing inspiratory airflow in order to provide an inspiratory assist to the muscles of respiration. Indeed, NIPPV therapy in adult patients has been shown to improve tidal volume and minute ventilation by 33% and 17%, respectively. The use of NIPPV therapy during sleep enhances gas exchange and decreases the work of breathing. Both exercise tolerance and quality of life improve.

As pulmonary function declines, respiratory support during wakefulness may also be indicated. In the past, children with deteriorating respiratory status were supported with a succession of increasingly complex medical devices, culminating in tracheostomy and invasive ventilation. Parents and children currently may prefer to continue with NIPPV therapy, in order to avoid tracheostomy and thereby preserve phonation and swallowing functions important to their quality of life. Children who require both nocturnal and diurnal NIPPV are at very high risk for respiratory complications, because their vital capacity is usually less than 25% predicted, and they have difficulty handling secretions. Failure of home NIV therapy occurs more often in these children.

Children requiring domiciliary NIPPV therapy are supported and managed in comprehensive home ventilation programs. Medical supervision is provided by sleep physicians and respiriologists who provide periodic review, including scheduled overnight polysomnography studies. Therefore, preoperative consultation with these physicians is important, because they form the liaison with the home ventilation program.

**An Overview of the Medical Devices Available to Deliver Domiciliary NIV Therapy.** The acronym NIV is frequently applied to both the therapy and the device that delivers the therapy. There are presently more than two dozen brands of medical devices to deliver NIV therapy, varying in biomedical design complexity from simple sleep apnea equipment to sophisticated home and critical care ventilators with NIV capabilities.

Regulatory bodies classify medical devices by risk. Class I medical devices are not intended for use in sustaining or sup-
porting life and do not present a risk for injury. Examples of Class I medical devices are stethoscopes, hearing aids and wheelchairs. Class II medical devices are intended to support life, are required to meet mandatory performance standards, are designed to perform without causing injury, and are subject to postmarket surveillance. Examples of Class II medical devices are infusion pumps and ventilators. Medical devices to deliver NIV therapy include both Class I and Class II medical devices. Table 1 lists the design features of Class I and Class II medical devices available for home noninvasive ventilation.

| ISO Standard | Medical Devices Classification | Design | Intended to deliver Positive Airway Pressure Device | Intended for use during spontaneous breathing | Intended to be life supporting | Intended for use during apnea | Intended for use with a nonhermetic mask design | Intended for use with a tracheal tube | Monitors | Monitoring Parameters | Protection Devices | Maximum NIV System Pressure | Means to Prevent Invasive Ventilation | High-Inspiratory Pressure | Continuing Positive Pressure | High and Low Expiratory Tidal Volume and Minute Ventilation | Hypoventilation | High and Low End-Tidal CO₂ | Purchase Price (USD) |
|--------------|--------------------------------|--------|------------------------------------------------------|---------------------------------------------|-----------------------------|-----------------------------|--------------------------------------------|---------------------------------|---------|----------------------|-----------------------------|--------------------------|-------------------------------|-----------------------|--------------------------|------------------------|---------------------|
| ISO 17510–1: 2007 | Class I | Yes | Positive airway pressure | Yes | No | Yes | NIV mode option | No | Airway pressure monitor | Mandatory | 40 cm H₂O (40 hPa) | Mandatory | Not required | Not required | Not required | Not required | Not required | Not required | $2,000–$5,000 |
| ISO 17510–1: 2007 | Class I | Yes | Positive airway pressures | Yes | No | Yes | NIV mode option | No | Airway pressure monitor | Mandatory | 40 cm H₂O (40 hPa) | Mandatory | Not required | Not required | Not required | Not required | Not required | Not required | $6,000 |
| ISO 10651–6: 2004 | Class II | Positive airway pressure | Positive airway pressures | Positive airway pressure | Positive airway pressure | NIV mode option | Invasive ventilation mode option | Invasive ventilation mode option | Airway pressure monitor | Mandatory | 60 cm H₂O (60 hPa) | Mandatory | Expiratory tidal volume or expiratory minute ventilation or expiratory end-tidal carbon dioxide | ±20% actual value | If a capnometer present, alarms are mandatory | Not required | Not required | Not required | Not required | $6,000 |
| ISO 10651–2: 2004 | Class II | Positive airway pressure | Positive airway pressures | Positive airway pressure | Positive airway pressure | NIV mode option | NIV mode option | Airway pressure monitor | Mandatory | 60 cm H₂O (60 hPa) | Mandatory | Expiratory tidal volume or expiratory minute ventilation or expiratory end-tidal carbon dioxide | ±20% actual value | If a capnometer present, alarms are mandatory | Not required | Not required | Not required | Not required | $6,000 |

ISO = Organization for International Standardization; USD = United States dollars.
The purpose of this discussion, NIV systems complying with ISO 17510 Part 1 will be referred to as NIV devices. NIV systems complying with ISO 10651–6 or ISO 10651–2 will be referred to as ventilators with NIV capabilities. The same ventilator may be equipped with both noninvasive and invasive ventilation modalities.

The essential components of NIV systems are the flow generator, the breathing circuit, and the NIV mask. (fig. 1) All NIV systems are designed to deliver a therapeutic airway pressure and achieve a positive airway pressure by directing airflow into a mask equipped with a high-resistance exhaust port or expiratory valve. Whereas the driving pressure for the flow generator in critical care ventilators is supplied from either pipelines, compressed gas, or air compressors, in home NIV systems, it is supplied by a servo-controlled air compressor.

Two different circuits – double- and single-limb circuits — are available for use in NIV systems, as illustrated in figure 2.5 In double-limb circuits, there are separate inspiratory and expiratory breathing pathways and an expiratory valve (fig. 2A). In single-limb circuits, the inspiratory and expiratory breathing pathway share a common conduit. Single-limb circuits lack an expiratory valve (figs. 2BC, BD), and in single-limb circuits, the expiratory flow cannot be directly measured. In double-limb circuits, the expiratory flow can only be measured directly if the spirometer is interposed between the expiratory valve and the patient (fig. 2A2). Single-limb circuits are the usual circuit used to deliver home NIV therapy.

NIV systems lack a reservoir bag, a design feature that facilitates the delivery of a constant positive airway pressure throughout the phases of the respiration. However, the absence of a reservoir bag requires a design that ensures an adequate peak inspiratory flow rate. These design features include a high rate of gas flow and/or an alternate inspiratory pathway. In normal operation, the level of inspiratory gas flow delivered through the breathing tube ranges from 20 to 60 l/min.

The NIV mask complies with ISO 17510–2.25 The NIV mask is used interchangeably with Class I NIV devices and Class II ventilators with NIV capabilities. Delivery of NIV therapy relies on a nonhermetic technique and requires a high-resistance exhaust port/expiratory valve located on the mask or mask connection. The exhaust port discharges a continuous intentional leak during normal operating conditions. In addition, the imperfect seal of the mask to the face is an additional source of leakage: the unintentional leak. The magnitude of the unintentional leak varies with the phase of respiration, with shifts in the mask position and with changes in the

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**Fig. 1.** Components of a single-limb circuit noninvasive ventilation system. The exhaust port may be located in the noninvasive ventilation mask or mask connection. Pressure and flow sensors are housed in the flow generator, which also contains a pressure regulation valve. NIV = noninvasive ventilation.

**Fig. 2.** Essential components of noninvasive ventilation (NIV) systems using double (AA, AB) and single (BD, BC) circuits. In all systems, the flow generator directs a high rate of gas flow through the inspiratory pathway to a NIV mask equipped with an expiratory valve interposed in the circuit (AA, AB) or exhaust port (BC, BD). When applied to the face, this results in an intentional leak and pressurizes the NIV system. Expiratory airflow is only measurable when the flow meter is located between the patient and the expiratory valve (A2). In the three other configurations, expiratory airflow cannot be measured directly. NIV = noninvasive ventilation. Reproduced with permission from Rabec et al.,5 modified from Perrin C, Jullien V, Lemoigne F: Aspects pratiques et techniques de la ventilation non invasive. Rev Mal Respi 2004; 21(3):556–66.
compliance and resistance of the upper airway and respiratory system. Modern NIV devices are equipped with microprocessors and sophisticated proprietary algorithms that adjust the rate of gas flow to compensate for the variable unintentional leak.

Although NIV systems will fit a 15 mm/22 mm connector, they are not intended for use with tracheal tubes. The leak around an invasive uncuffed tracheostomy tube is insufficient to adequately discharge the high rate of inspiratory gas flow, in excess of 20 l/min, without injury. Home ventilators for invasive ventilation are indicated in tracheostomized patients.23

NIV systems have three additional design features. First, all NIV devices are equipped with a pressure sensor located in the flow generator to detect high airway pressure. Second, all NIV systems are equipped with a pressure regulation valve in the flow generator and design features to limit the maximum pressure to 40 cm H₂O in Class 1 NIV devices and to 60 cm H₂O in Class II ventilators with NIV capabilities (table 1). And third, home NIV devices are intended for dedicated use in single patient and are not designed to function with in-line filters.

**CPAP Devices.** CPAP devices are designed to deliver a continuous distending pressure throughout the patient’s respiratory cycle.26 The minimum performance for the delivery of positive airway pressure is ± 1.5 cm H₂O of the set pressure.22,27

**NIPPV Systems.** NIPPV devices are designed to deliver a cyclical application of two levels of positive pressure: IPAP and EPAP. This requires design features that sense the phase of respiration8,26 and trigger the transitions between IPAP and EPAP.

### The Inspiratory Trigger between EPAP and IPAP

The trigger for IPAP is initiated by the patient’s inspiratory effort and is detected by a change in airway pressure or gas flow within the NIV system.5 Most modern NIV systems achieve the transitions between IPAP and EPAP with flow-based triggers. Sophisticated proprietary algorithms have been developed to detect phasic changes in gas flow, waveforms, and flow reversal(s). Asynchrony between the child and NIV system during the inspiratory trigger is common especially during sleep, and therefore some homecare NIV protocols require a backup ventilation rate. The selected backup rate is often set at a rate higher than the child’s spontaneous rate during sleep, effectively instituting a controlled mode of ventilator support.8 NIV devices, however, are not intended for use in apneic patients (table 1).

### The Expiratory Trigger between IPAP and EPAP

The trigger for expiration may be either a function of time or a threshold decline in inspiratory flow.8 In children, a maximum inspiratory time of 0.3–0.5 s is often used.

The sensitivity of the trigger function represents an important limit to the use of NIPPV in small children, particularly those with poor respiratory muscle strength,18,26,28 because their low rates of inspiratory flow may be insufficient to initiate the inspiratory trigger.8 This is one of the reasons NIV devices are not intended for use in patients weighing less than 30 kg. For these children, ventilators with NIV capabilities offer a better option.

### Pressure-targeted NIPPV Systems

Most bilevel pressure NIV systems achieve the IPAP level by increasing the rate of gas flow during inspiration, until the predefined positive airway pressure target is attained. It is beyond the scope of this review to discuss all NIV modalities, and readers are directed to a comprehensive review in Thorax.5 The two basic NIV modalities are pressure-targeted NIPPV and volume-targeted NIPPV. The majority of home NIV systems use pressure-targeted modalities.

The EPAP is titrated to eliminate obstructive airway events, and IPAP is titrated to attenuate hypercarbia during sleep. The usual levels of IPAP and EPAP range from 10 to 16 cm H₂O and from 4 to 5 cm H₂O, respectively. NIPPV devices have less pressure-generating capacity than ventilators.7 The magnitude of inspiratory assist depends on the difference between IPAP and EPAP.18 However, the NIV system–lung assembly does not behave as a single compartment model, because the upper airway presents a variable resistance. Increasing the airway pressure may not increase the effective ventilation to the patient.5

### Volume-targeted Devices

Volume-targeted NIPPV devices deliver a set flow to the airway for a defined time interval or until a preset volume is obtained. The presence of leaks at the mask interface requires a design feature capable of delivering very large gas flows during the inspiratory phase of the respiratory cycle.8 These gas flow rates may exceed 150 l/min.

### The Interface and the NIV Mask

NIV therapy is delivered with a nasal or full-face mask. The NIV mask design is deliberately nonhermetic, allowing the mask to be adjusted to comfort. The mask must be soft and secure and yet allow for sweating. Velcro straps applied too tightly to a full-face mask may displace the mandible backward, allowing the tongue to obstruct the upper airway.8 In addition, a tight, ill-fitted mask risks skin injury and ulceration. Too tight a mask, worn over many years, may adversely affect the growth and development of facial bones.1 Although the patient connection port may be a 15 mm/22 mm connector,22,25 NIV systems are not designed for use with an endotracheal tube, tracheostomy tube, laryngeal mask, or anesthesia mask. If the expiratory trigger failed and the high inspiratory gas flow continued during expiration, the patient could become hyperinflated, risking barotrauma and injury.
For children, nasal masks are preferred, in part to minimize the apparatus dead space and facilitate the trigger functions of the NIV systems. During normal operation, mouth breathing increases the gas leakage, and parents may devise ways and means to ensure the mouth remains closed during sleep (i.e., chin straps).

In pressure-targeted NIV systems, the magnitude of the inspiratory assist decreases during perturbations such as increased upper airway resistance, decreased lung compliance, or increased unintentional leak. Modern NIV systems offer a “volume guarantee” mode that will deliver a minimum level of ventilation when such perturbations occur. The efficacy of the “volume guarantee” mode was recently tested in six NIV systems. Perturbations sufficient to decrease tidal volume (VT) were determined. The ventilators were set in the “volume guarantee” mode to deliver a minimum VT. The response to a perturbation was to increase IPAP (fig. 3). With perturbations in airway resistance or lung compliance, five of six NIV systems achieved the guaranteed minimum VT. However, when the unintentional leak increased, only one NIV system achieved it. Auto-triggering, or the delivery of a breath cycle without the patient triggering a breath, occurred frequently during large unintentional leaks. In addition, a large unintentional leak may preclude attainment of the preset IPAP, and the NIV system may not cycle to EPAP, allowing the high rate of gas flow to continue even if the patient ceases to inhale. This high gas flow rate will impede exhalation, increasing the work of breathing and risking barotraumas, gastric insufflation, and aspiration of stomach contents. Large unintentional leaks at the mask interface are particularly common in children.

**Rebreathing Potential in NIV Devices**

Although the ECRI Institute considers the patient-supplied NIV mask less hazardous than the NIV device, it is the design of the NIV mask that influences the risk of rebreathing. Washout of carbon dioxide is more efficient if the exhaust port is located within the mask. Dual-limb NIV systems mitigate the degree of rebreathing by using an expiratory valve and separating the inspiratory and expiratory pathways. In a single-limb NIV system, the inspiratory and expiratory breathing pathway share a
common conduit (fig. 4). As the exhaust port purposely offers a high resistance, the expiratory pathway may include the low-resistance breathing tube. A high rate of gas flow is required to prevent rebreathing during normal use.30 The risk of rebreathing decreases with increasing airway pressure (higher gas flows). The NIV systems are designed such that during normal use, the time-weighted average for inspired carbon dioxide is 1%, a limit which harmonizes with that allowed in occupational health exposure.25 A minimum mandatory EPAP level of 3 or 4 cm H2O (gas flow around 20 l/min) is needed to ensure adequate washout of exhaled carbon dioxide.

The risk of rebreathing is maximal when inspiratory gas flow ceases. In the event of a power failure, the inspired carbon dioxide level will rise precipitously, coincident with a fall in inspired oxygen (fig. 5). Although a battery reserve should protect from electrical power failure, battery life is difficult to predict and often brief. Class I medical devices may not be equipped with a battery backup. Therefore, the design of NIV equipment incorporates a means to allow spontaneous breathing in the event of a device failure. This may be accomplished by including an antiasphyxiation valve in the NIV mask. A nasal NIV mask should have less risk of asphyxiation because the child can initiate mouth breathing. However, mouth breathing may not be possible if chin straps are used. In NIV systems, the short-term exposure limit for inhaled carbon dioxide is 3% (about 22 mmHg), a limit that assumes that the physiologic arousal response will be sufficient to rouse the patient.22,25

**Inspired Oxygen Concentration**

During power failure, with cessation of gas flow, the rebreathing of exhaled gases will allow a hypoxic admixture to accumulate in the breathing tube (fig. 5).30 In the event of a power failure, it is expected that the sleeping patient will rouse and remove the NIV mask.

During normal use, supplemental oxygen may be intentionally delivered into the breathing tube or the mask interface. Several factors influence the inspired oxygen concentration, including the NIV modality, the rate of gas flow rate, the minute ventilation, and the location at which oxygen is delivered into the NIV system. In healthy volunteers on NIV therapy, a maximum inspired oxygen concentration of 67% was reported.31 However, the inspiratory oxygen concentration achieved in patients on NIV devices is often less than 50%.

**Perioperative Management Conundrums in Patients Supported with Domiciliary NIV**

**Patient Selection.** The safe use of NIV to support ventilation following surgery requires selection of both appropriate patients and NIV systems, and a recognition that the clinical scenario in the hospital differs from that in the home environment.

In hospitalized patients, eligibility criteria for NIV support are the ability to call for help, to pass 15 min off NIV without respiratory decompensation, and to maintain oxygen saturation with modest inspired oxygen concentrations.1,32 Health Canada advises that patients who have a limited ability to adjust or remove the NIV mask should be attended at all times.9 NIV therapy is contraindicated if children are apneic, unable to protect their own airway, unable to maintain the patency of the upper airway, have a reduced level of consciousness, or have an unstable respiratory status.33

**Can Children Supported with Home NIV Systems Be Managed in Ambulatory Surgical Programs?**

Class I NIV devices and some Class II ventilators with NIV capabilities are not intended to support life (table 1). These
NIV systems rely on the patient’s reflex and arousal mechanisms to monitor the function of the NIV system. Sedative and analgesic medication may blunt arousal and reflex defenses. Because the safe use of NIV systems is predicated on an intact physiologic defense system, children on domiciliary NIV systems should not be discharged home until these protective and defense mechanisms have returned (fig. 6). Children with continuous home NIPPV therapy have a limited respiratory reserve and are at extreme risk for respiratory complications following anesthesia and surgery. These children are poor candidates for ambulatory programs.13

Which Surgical Procedures?
As NIV systems include the upper airway in the breathing pathway, compromise of nasopharyngeal airway patency may limit the efficacy of NIV therapy. Surgeries associated with upper airway edema, bleeding, nasal congestion, and surgical packings may obstruct the upper airway, and affect the efficacy of NIV therapy. Pulmonary function may be affected in the postoperative period, and supplemental oxygen may be required. In addition, the settings for the NIV system may require adjustment. IPAP levels of 10–16 cm H₂O usually provide sufficient support. Children become uncomfortable if IPAP settings exceed 20 cm H₂O.18 The maximum IPAP for preadolescent children is 20 cm H₂O, and for adolescents the maximum is 30 cm H₂O.34 Higher levels of IPAP may increase the gas leak, and the straps securing the NIV mask may require adjustment.

Can NIV Be Safely Administered on Hospital Wards?
Expertise of Healthcare Providers. The challenges of delivering NIPPV therapy on hospital wards are illustrated by two published scenarios in patients with advanced cystic fibrosis. An adolescent on continuous NIPPV was found unresponsive on the floor, having removed the NIPPV system without notifying his nurse. A young adult with chronic respiratory failure developed agitation because of respiratory acidosis. Trigger asynchrony was suspected, and she was treated with intravenous sedation. The respiratory status further deteriorated, requiring invasive ventilation.17

Because NIV devices are used in a home environment, their use on hospital wards might seem reasonable. However, mishaps during NIV therapy have been reported in hospitalized patients. In one case, the CPAP device was misassembled.35 Another patient died because of NIV system failure, and a third death was linked to NIV system-related infection.3 Health Canada advises that medical staff caring for patients supported by NIV systems should be knowledgeable of the capacities and limitations of NIV systems.3 The safe use of NIV therapy on the wards requires the selection of patients with stable respiratory failure, the availability of expert and adequately trained staff throughout a 24-h period, adequate monitoring, and immediate access to invasive ventilation in the event of respiratory deterioration.1,32

In addition, the settings for NIV systems that are adequate in the home environment may not be therapeutic in the postoperative period, as illustrated in figures from three consecutive nocturnal NIV recordings (figs. 7 and 8). Figure 7A is a representative baseline trace of internally logged data from a home NIV system; the set EPAP and IPAP levels of 4 and 15 cm H₂O, respectively, were achieved throughout 13 h of use. During the majority of the record, there were no patient-triggered breaths, and ventilation was supported entirely with the NIV system, at a backup rate of 25 breaths/min. The estimated tidal volume was 277 ml and the estimated minute ventilation was 6.8 l/min. Following surgery (fig. 7B), the set EPAP and IPAP levels were identical and achieved throughout 18 h of use. However, patient-triggered breaths are now present throughout the record, likely reflecting a combination of wakefulness and pain. The recorded tidal volume has decreased to 202 ml. During the following night (fig. 8), the set EPAP and IPAP levels were unchanged and achieved throughout the 22 h of use, but the recorded tidal volume has now decreased to 98 ml. The levels of positive airway pressure, which were therapeutic in the home environment, are now inadequate.

Monitoring and Alarms: Do NIV Systems Monitor Ventilation?
All NIV systems are required to measure airway pressure, and the majority of modern NIV systems log parameters of airway pressure for periodic review. However, a data log is not synonymous with a monitor. Class I medical devices are not designed to monitor patients, and patient well-being is the prime indicator that an NIV device is functioning. A feature that distinguishes the Class II NIV systems from Class I NIV devices is the requirement, in the former, to monitor the ventilation of the patient (table 1). Class II ventilators for ventilator-dependant patients are intended to deliver both positive airway pressure and ventilation and are therefore designed appropriately.24

Home ventilation programs define ineffective ventilation by the failure to attain the set airway pressures, an excessive
unintentional leak, and frequent desaturation indices. Capnography is not used in the home environment. Some manufacturers have developed sophisticated proprietary algorithms that assess gas flows and estimate the unintentional leaks of the NIV system. In addition, there are proprietary algorithms that estimate the delivered minute ventilation and VT of the patient. However, the accuracy and clinical relevance of the reported physiologic parameters lack validation. Recent bench studies suggest that VT is underestimated, especially at high IPAP pressures. In the home environment, there is no need for bedside reporting of data, because the efficacy of the NIV therapy is assessed by patient well-being and periodic review of the internally logged data. In hospitalized patients it may prove useful to review this internally logged data, but currently this feature is not readily available at the bedside.

If Patients on Domiciliary NIV Are Not Being Monitored at Home, Do They Need to Be Monitored While in the Hospital?

Unless the ventilation is being monitored at the bedside, changes in the ventilatory status may not be obvious. Health Canada advises that hospitalized patients supported with NIV systems must be monitored with oxygen saturation and vital signs. Arterial or capillary blood gases may also be indicated. Although capnography is available in hospitals, its accuracy in NIV systems may be influenced by dead space, VT, and the high rate of gas flow. Transcutaneous measurement of carbon dioxide may be more useful in the hospital environment.

Should Children Be Permitted the Use of Their Own Domiciliary NIV Systems?

Of the task force’s consultants charged with developing guidelines for the perioperative management of patients with OSA, 79% strongly agreed that patients should be restarted on their home NIV therapy as soon as feasible after surgery. Parents and children often request the use their own NIV system while in the hospital, citing differences among NIV systems in leakage, trigger sensitivities, type of circuit, and position of the exhaust port – all of which may affect the quality of ventilatory support. In the home environment, the NIV systems are reported to be robust and reliable, and this request may seem reasonable. However, whereas the use of patient-supplied NIV masks is condoned, the ECRI Institute cautions hospitals against the use of patient-supplied NIV systems.

Most countries lack a centralized database for reporting problems with home NIV systems. The lack of reporting is not evidence of safety, as Health Canada cautions that rates for spontaneously reported adverse incidents (with NIV systems) are presumed to underestimate the risk. A multicenter evaluation of 22 conventional NIV systems reported significant differences between the set parameters and the actual values. In 17% of patients, the index of ventilator error exceeded 20%. In addition, home NIV systems underperform when subjected to high-level re-
quirements similar to those which may occur during the postoperative period.43 Another major issue with patient-supplied NIV systems is that the alarms have frequently been disabled, because most (i.e., low VT) enunciate so frequently they constitute a nuisance and disrupt sleep.33,43 A feature that distinguishes the Class II NIV systems from Class I NIV devices is the requirement, in the former, to enunciate alarm conditions intended to summon help (table 1). Disabling alarms on ventilators with NIV capabilities negates the safety design features that distinguish Class II from Class I medical devices. In the postoperative period, when the patient’s clinical state may change rapidly, ventilators with NIPPV capabilities, which are designed for ventilator-dependant patients, may provide more reliable respiratory support. At some point before discharge, transition to a domiciliary NIV system and liaison with the home ventilation program is required (fig. 9).

**Recommendations**

Anesthesiologists increasingly encounter children who are supported on home NIV therapy and are asked for advice on their perioperative management. The optimal transition from sedation and/or general anesthesia to their home NIV system is an area of study, and practice guidelines for the safe management of patients supported with home NIV systems have yet to be developed. Our recommendations are listed in table 2. As the intensive care unit is the only location in our hospital with continuously available expertise in NIV systems, all children requiring NIV therapy in the postoperative period are initially admitted to the intensive care unit following anesthesia. Our caseload of the children on home NIV therapy is small, and this requirement has not proven problematic. Recovery of both defensive and protective reflexes and transition to the home NIV system should occur before discharge from hospital.

**Summary**

Treatment of refractory obstructive sleep apnea and chronic respiratory failure with home NIV is now standard pediatric practice. Anesthetic and analgesic medications induce apnea, depress respiratory drive, decrease compliance of the respira-
event, increase the collapsibility of the upper airway, and alter the sensorium, thereby compromising NIV therapy. Just as knowledge of pharmacology underlies the safe prescription of medication, so too knowledge of biomedical design underlies the safe prescription of NIV medical devices. The medical device design requirements developed by the Organization for International Standardization provide a framework to rationalize our choice of the medical device to support ventilation in the postoperative patient who has been supported with a domiciliary NIV system.

Table 2. Recommendations for the Perioperative Management of Children Supported with Home Noninvasive Ventilation Therapy

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<th>Recommendations</th>
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<td>1. Preoperative consultation with respiratory medicine.</td>
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<td>2. Postoperative admission to the intensive care unit.</td>
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<td>3. Support with the appropriate NIV system designed to enunciate the relevant alarm conditions.</td>
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<td>4. Independent monitoring of the oxygen saturation and the cardiorespiratory status of the patient.</td>
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<td>5. Transition to the home NIV system prior to discharge home.</td>
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<td>6. Liaison with the home ventilation program or responsible physician prior to discharge home.</td>
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NIV = noninvasive ventilation.

References

21. Young AC, Wilson JW, Kotsimbos TC, Naughton MT: Ran-
domised placebo controlled trial of non-invasive ventilation for hypercapnia in cystic fibrosis. Thorax 2008; 63:72–7