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# **Respiratory Care Protocols in Neonatal Intensive Care**

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Additional information is available at the end of the chapter

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## **Abstract**

Neonatal respiratory care involves physicians with variable backgrounds treating multiple respiratory problems and populations with a number of invasive and non-invasive devices and strategies. Unfortunately, there is a lack of strong evidence to guide the most adequate management for several specific situations. Altogether, this complexity leads to significant practice variability that can affect patient and health care outcomes. Respiratory care protocols, guided by evidence and/or consensus, are an attractive solution to promote standardization of care and reduction of unnecessary practice variations. Indeed, despite the limited evidence supporting the use of respiratory protocols in neonates, a significant number of units have already developed and implemented them into clinical practice. Respiratory care protocols appear to promote evidence-based practices, discourage outdated approaches and ultimately improve patient safety.

**Keywords:** neonates, protocols, respiratory support, mechanical ventilation, intensive care

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## **1. Introduction**

The hallmark of neonatology relies on adequate provision of respiratory care, most commonly in the form of noninvasive respiratory support or mechanical ventilation (MV). Also, adjunctive therapies such as surfactant, caffeine, postnatal steroids and inhaled nitric oxide play important roles. In the past decade, a large number of strategies to guide respiratory care practices have been investigated in an attempt to improve neonatal short- and long-term outcomes, including length of MV, extubation failure rates, bronchopulmonary dysplasia (BPD) and neurodevelopment. Unfortunately, there is often limited or conflicting evidence to guide clinicians, leading to highly variable practices and a wide display of outcomes across

neonatal intensive care units (NICUs). One way to decrease unnecessary variations in practice is through the use of clinical protocols. The objective of this chapter is to (1) describe the variability of respiratory care practices in neonatology; (2) evaluate the impact of practice variability on patient and health care outcomes; (3) review the evidence for using respiratory care protocols in neonates; and (4) provide an overview on how to develop and implement these protocols in the NICU.

## 2. Variability of respiratory care practices in neonatology

In the modern era of neonatology, with the introduction of many new technologies and adjunctive therapies, the provision of adequate respiratory care has become very complex and challenging. Several local, national and international surveys have been undertaken to describe how these therapies are utilized across NICUs, consistently revealing wide intra- and inter-center variability.

### 2.1. Respiratory care management in the delivery room

Approximately 10% of neonates require some degree of respiratory assistance after birth [1]. As an inadequate delivery of respiratory support may have serious repercussions, it is crucial for health care providers to have a solid foundation in neonatal resuscitation while staying up-to-date with recent advances in the field. A number of national and international expert consortiums regularly publish evidence-based guidelines to help providers during this critical period [1]. Despite these recommendations, surveys from around the world continue to demonstrate wide variations in many aspects of respiratory care management in the delivery room.

The most striking illustration of variability is ventilation during neonatal resuscitation. Units provide positive pressure ventilation using various methods, including the flow-inflating bag (2–63%), self-inflating bag (6–96%), T-piece/Neopuff (1–79%) and ventilator (16–49%) [2–9]. These can be delivered via face mask, binasal prongs, single nasal prong or a nasopharyngeal tube. Many institutions have more than one device at their disposal. Although positive-end-expiratory pressure (PEEP) is now commonly used during positive pressure ventilation, many centers that use the self-inflating bag do not apply it with a PEEP valve or manometer [6]. In addition, delivered peak inflation pressures vary with regard to the maximal level and duration of the inflation [5, 8]. Continuous positive airway pressure (CPAP) in the delivery room has gained popularity over the past years, particularly for the preterm population. But its use varies between 50 and 85% across countries, with units setting different gestational age thresholds (anywhere from 24–32 weeks) above which they would attempt CPAP [2, 3, 5, 9]. For those infants who get intubated, 3–45% of units have reported using CO<sub>2</sub> detectors [4, 6–9]. Moreover, there are variations in the preferred routes of intubation (oral vs. nasal) and types of endotracheal tubes used (straight vs. shouldered) [5].

The second most prominent source of variability in the delivery room relates to oxygenation. Despite evidence-based recommendations on the use of pulse oximetry (PO), oxygen blenders

and resuscitation of term infants with room air [1], some units have not yet adopted these practices. Routine use of PO and O<sub>2</sub> blenders ranges from 30 to 100% and 36 to 100% across units, respectively [2, 5–10]. Although guidelines recommend preductal saturation measurements, one survey showed that only 37% of units placed their saturation probes correctly [3]. Similarly, 7–56% of units have been reported to initiate resuscitation in 100% oxygen [3, 4, 7, 10]. In the case of preterm infants, the starting concentration of oxygen varies considerably (between 21 and 100%), with some providers starting high and tapering down and others doing the contrary [8]. Oxygen is commonly titrated based on predefined oxygen saturation targets, but some units still adjust according to color and heart rate [6].

## 2.2. Invasive mechanical ventilation

With the rapid advent of technology, clinicians can now choose from a wide range of ventilators and modalities for invasive MV. Some surveys have reported as many as 12 different brands of ventilators for delivering conventional MV and at least 4 different types of machines for providing high-frequency oscillatory ventilation (HFOV), with many units having more than one type at their disposal [11–13]. There are currently over 10 different MV modes available, including assist control (pressure or volume controlled), intermittent mandatory ventilation (with or without synchronization, with or without pressure support), HFOV (with or without volume control), high-frequency jet ventilation and neurally adjusted ventilatory assist (NAVA). Use of all these ventilators and modalities is rarely guided by patient disease or best evidence, but rather by availability, familiarity and personal preferences [11–16].

A noticeable observation from recent surveys reveals that volume-targeted ventilation has yet to gain widespread adoption during MV, despite established evidence for its use as a lung-protective strategy [17]. There are significant geographical variations in volume-targeted ventilation use, ranging from 5 to 60% [12–14, 16, 18, 19]. With regard to the preset tidal volume ( $V_T$ ), the recommended target is generally 4–7ml/kg. However, surveys have demonstrated that some units use  $V_T$  targets as low as 3–4ml/kg and as high as 10ml/kg [18, 19]. Another prospective observational study showed that as many as 18% of units used  $V_T$  levels higher than 7ml/kg [12]. These extremes of low and excessive  $V_T$  may predispose to inadequate ventilation and volutrauma, respectively.

Furthermore, tools used for monitoring and titrating MV settings are quite heterogeneous. For instance, gas exchange can be monitored using PaCO<sub>2</sub> levels in the blood, transcutaneous CO<sub>2</sub>, end tidal CO<sub>2</sub> or near-infrared spectroscopy [16, 20]. There is generally no consensus on the blood gas route (venous, arterial or capillary), frequency of sampling and thresholds for titrating. Although some evidence suggests that permissive hypercapnia may be a lung-protective strategy during MV, a recent survey in the USA showed that clinicians aimed for various target PCO<sub>2</sub> levels, anywhere between 45 and 65 mmHg [21]. Ventilator settings are also titrated in many different ways. In one Canadian survey, PEEP could be titrated on the basis of oxygen saturation, pulse oximetry, blood gas, fraction of inspired oxygen (FiO<sub>2</sub>) or chest x-ray findings [16]. The indications and frequency of performing chest x-rays in intubated neonates are also rarely delineated and subject to individual preferences.

There are many other aspects of MV that lend themselves to practice inconsistencies. Endotracheal tubes (ETTs) are secured using various taping methods. Infants are suctioned via the ETT at different frequencies and techniques. Practices relating to infant positioning (supine vs. prone) or the ability to do kangaroo care during MV are also nurse or clinician dependent. Most importantly, the use of sedation during MV is so controversial that it has led to very changeable practices; some clinicians always provide opiates and/or sedatives to intubated patients, while others sometimes or never use it [14, 15].

### 2.3. Peri-extubation practices

In order to limit complications associated with MV, infants are often extubated as early as possible. The process of extubation is quite complex and consists of three important steps: weaning from MV, assessment of extubation readiness and provision of post-extubation respiratory support. Significant variations in practice exist for all components of this process, with decisions often being physician dependent and not always evidence based. For instance, synchronized intermittent mandatory ventilation (SIMV) appears to be the most commonly used weaning mode across surveys [13, 14, 16], despite the evidence that assist control ventilation confers more homogeneous  $V_T$  and faster weaning when compared to SIMV [22]. Furthermore, in a recent international survey focused on extremely preterm infants, extubation readiness was primarily assessed based on the subjective interpretation of ventilator settings, blood gases and overall clinical stability [23]. In addition, 16% of infants were extubated on the basis of passing a spontaneous breathing trial, although the trial was often conducted in variable ways. The timing of extubation was extremely variable, with some units removing the ETT immediately after surfactant administration while others only after 2 weeks of MV. Finally, 10% of the centers still reported extubating extremely preterm infants to low-flow nasal cannula, oxyhood or no respiratory support despite the undisputed evidence favoring the use of noninvasive ventilation in this population [24].

### 2.4. Noninvasive ventilation

*Continuous positive airway pressure*—Since its discovery in the late 1970s, CPAP has been extensively studied in neonates. Consequently, it is by far the most widely used noninvasive mode across the world. Although CPAP has been well established and widely adopted for the treatment of apnea of prematurity and following extubation of preterm infants, its use as a primary therapy for respiratory distress syndrome (RDS) has only recently gained attraction. A recent study comparing epidemiological data from the Vermont Oxford and Italian Neonatal Networks revealed significantly high coefficients of variation in the use of CPAP as a primary therapy, ranging from 0 to 80% [25]. To provide CPAP, a variety of devices (ventilator, infant flow SiPAP or bubble) and interfaces (nasal prongs, nasal mask, nasopharyngeal tubes, nasal cannula) are used [11, 26]. There is no clear consensus on the level of CPAP to be applied as well as on how to wean and discontinue CPAP therapy. For instance, cycling off CPAP and transitioning from CPAP to high-flow nasal cannula (HFNC) therapy are common non-evidence-based practices.



*Nasal intermittent positive pressure ventilation (NIPPV)* — This has also gained popularity, with rates of use varying from 18 to 88% in different parts of the world [25–28]. It is most commonly applied as a rescue mode for infants who fail CPAP, to prevent intubation in infants with RDS or immediately after extubation. This variability in usage mainly stems from conflicting evidence on its effectiveness as well as limited understanding of its mechanisms of action, clinical indications and optimal means of delivering the pressures. Similar to CPAP, units may have at their disposal up to five different devices and interfaces for delivering NIPPV [26–28]. Synchronized NIPPV is still used by some units, but for the majority it is no longer commercially available [27, 28]. This is particularly important because the only studies demonstrating physiological and clinical benefits have used synchronized NIPPV [28]. Furthermore, there is no consensus on what constitutes best settings (peak inflation pressure, PEEP and rate) and how to optimally wean NIPPV.

*High-flow nasal cannula* — Well before any clinical trials had established its safety and effectiveness, high-flow nasal cannula (HFNC) had been widely used across units. Surveys revealed that between 50 and 77% of units were using it [25, 29, 30]. The most common indication was in the immediate post-extubation period. In two surveys, 33% of extremely preterm infants ( $\leq 28$  weeks) and 12% of infants with birth weight  $\leq 1$  kg were extubated directly to HFNC, respectively [23, 30]. This is particularly concerning, given the lack of evidence for infants below 26 weeks and experts cautioning against its routine use in this population [31]. Another popular application for HFNC is as an alternative to CPAP or as a weaning step between CPAP and no respiratory support. However, no evidence currently exists to support any of those practices [32]. With regard to the actual delivery of HFNC, current evidence (from the literature and manufacturers) recommends using no more than 8 L of flow and a nasal cannula that allow some degree of leakage around the nares (around 50%). In spite of this, there is wide variability in HFNC delivery; one survey reported that as many as 15% use maximal flows greater than 8 L, over half of the respondents apply nasal cannula that exactly fits the nostrils and 23% apply measures to keep the mouth closed [29]. All these actions have the potential to deliver unreliable and dangerously high levels of pressure.

*Other modes of noninvasive ventilation* — More novel noninvasive modes have recently made their way into clinical practice despite the lack of evidence to support their use. Two such examples include noninvasive HFOV and noninvasive NAVA. A recent European survey reported that 17% were using noninvasive HFOV for diverse indications, mainly for CPAP failure or as primary therapy. There were significant variations in the types of equipment, interfaces and settings used for its delivery, with little information about its safety profile [33]. Similarly, noninvasive NAVA is increasingly applied in many NICUs across North America using evidence mainly based from animal data, retrospective clinical studies and case series [34].

## 2.5. Adjuvant therapies

*Caffeine* — A succession of animal, pharmacological and clinical evidence over the years has led to widespread caffeine use in neonates. The most influential publication of all was the large, multicenter Caffeine for Apnea of Prematurity (CAP) trial, which showed that caffeine significantly reduced incidence of bronchopulmonary dysplasia and cerebral palsy in preterm

infants [35, 36]. Nonetheless, in the real world, caffeine practices continue to be highly variable and not always reflective of current evidence. For example, two recent surveys that reported 54 and 77% of units ensured that extremely preterm infants were loaded with caffeine prior to extubation [14, 23]. This is contrary to recommendations advocating for caffeine use in order to improve chances of successful extubations in preterm infants [37]. As another example, the use of prophylactic caffeine for the prevention of apnea has been heavily debated. The latest Cochrane review in 2010 [38] did not support routine use of prophylactic caffeine, but a series of recent retrospective studies have shown that early administration of caffeine (in the first 48 h of life) significantly reduced length of MV and improved short-term respiratory outcomes in preterm infants [39, 40]. As a result, the off-label use of prophylactic caffeine has risen from 22% (at the time of the CAP trial) to 60–75% [39, 41, 42]. The first dose is given anytime between days 1 to 25 of life and for a duration ranging from 2 to 119 days [42]. There are also noticeable differences in practices related to monitoring and discontinuation of caffeine. Ten percent of units still routinely measure caffeine levels [41]. The timing of caffeine cessation often depends on the unit's prespecified gestational age cutoff (anywhere from 32 weeks to greater than 35 weeks). A significant proportion of units also discontinue caffeine once the infant has become apnea-free for 5–7 days (81%),  $\leq 4$  days (11%) or  $\geq 8$  days (8%) [41].

*Surfactant*—The introduction of surfactant is probably one of the most important and life-saving discoveries in the history of neonatology. It improved survival and reduced important morbidities associated with MV, especially for the extremely preterm population. However, the role of surfactant in everyday practice has markedly evolved over time. Originally, surfactant was mainly recommended as prophylaxis for all extremely preterm infants and was preferably administered in the first 2 hours of life [43]. Nowadays, clinicians are trying to avoid MV all together and are therefore looking for alternative ways to administer it using less invasive routes [44]. As such, use of prophylactic surfactant varies anywhere between 0 and 90% [10, 11, 14, 25, 45]. Most units use the intubation-surfactant-extubation method, but other strategies are increasingly tried [46]. When surfactant is provided as rescue therapy, clinicians use different clinical indications (e.g.,  $\text{FiO}_2$  thresholds), number of doses and methods of administration (e.g. infant's position, rate of infusion, pressures and lung recruitment maneuvers used pre- and post-administration) [14, 45, 46].

*Inhaled nitric oxide*—The use of iNO for persistent pulmonary hypertension and acute hypoxic respiratory failure has been comprehensively studied in late preterm and term infants. In spite of this, there exists wide practice variations related to iNO administration in this population. Clinicians assess illness severity in a variety of ways (e.g., oxygenation index, pre-post ductal saturation difference,  $\text{O}_2$  requirements and echocardiographic findings) and have different thresholds or indications to start iNO and use variable starting doses (5–20 ppm) and maximal doses (20–40 ppm) [47, 48]. Moreover, there is no standard approach for monitoring and weaning iNO (blood gases, oxygenation index, oxygen saturation and/or  $\text{O}_2$  needs), especially in patients who are non-responders to the therapy. The most striking observation of all is the rising off-label use of iNO in preterm infants less than 34 weeks gestation, despite firm position statements and consensus guidelines recommending against it. In fact, a number of surveys and large epidemiological studies have documented wide regional and inter-hospital varia-

tions in iNO use, indications, age of initiation, dosage and duration of therapy for this group [48–50]. This raises great concern, especially when iNO is associated with staggering health costs and has not been demonstrated to improve short- or long-term outcomes in this population, with potential to cause harm in the subset of extremely preterm infants less than 1000 g [51].

### 3. The impact of respiratory care practice variability

For the many reasons explained in the first session of this chapter, variability in respiratory care practices is extremely prevalent. The NICU is a fast-paced environment where decisions are often made on the go and clinicians do not always have the time or sufficient knowledge to make the most informed decisions. In addition, units are often restrained in their ability to adopt a certain practice by its cost, ease of use or resource requirements (space, personnel, etc.). Most importantly though, despite the abundant existing literature, the evidence to justify most respiratory care practices is often limited or conflicting, leading clinicians to interpret study results in various ways, or shape their practices according to different background experiences and personal beliefs.

There are many implications of practice variability on patient outcomes (**Box 1**). In cases where high-grade evidence exists to guide respiratory care practices, it is easy to perceive how deviations (e.g., evidence-based therapies are introduced too late, too soon or are misused for certain populations and conditions) can negatively affect patients. But, even in cases where the evidence is unclear, the mere presence of variability has been linked to marked differences in pulmonary morbidities across NICUs. For example, rates of extubation failure range from 20 to 70% in preterm infants [52, 53]; this means that units with low extubation failure rates may perhaps be exposing infants to prolonged periods of MV while units with high failure rates may be disconnecting infants from the ventilator too soon. Both prolonged MV and the need for reintubation have been associated with serious, preventable morbidities [54, 55]. In a similar way, rates of unplanned extubation vary between 1 and 80% depending on unit MV practices and ETT fixation methods [56]. These accidental extubations also expose infants to unnecessary complications, including hemodynamic instability, need for reintubation and prolonged MV [56]. Moreover, several benchmarking studies have demonstrated important variations in the incidence of BPD across centers, which persist even after adjusting for variables known to affect this outcome [57, 58]. Authors of these studies have suggested that differences in clinical practice may actually be affecting this clustering effect. Similar observations have been made for non-respiratory related outcomes, including survival and neonatal sepsis [59–61].

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#### Box 1.

Impact of respiratory care practice variability.

#### On patients



- Potential for using non-evidence-based practices
- Potential for increased errors and morbidities
- Unpredictable management
- Lack of continuity
- Parental distress

#### **In workplace**

- Increased costs
  - Increased resources
  - Confusion of health care team
  - Inconsistent learning environment for trainees
  - Reduced potential for quality control initiatives
- 

Practice variability has potentially negative consequences that go even beyond patient outcomes (**Box 1**). It is not uncommon for a single patient to be exposed to several ventilation modes or therapies throughout hospitalization, or for a family to receive conflicting opinions regarding their child's respiratory management. This could be a great source of anxiety for the parents and may weaken their alliance with the health care team. Besides, this could create a lot of confusion among nurses, respiratory therapists and trainees, leading to lesser opportunities for productive teaching or learning. Finally, with little continuity or predictability of management, it becomes quasi impossible to effectively audit respiratory care practices or perform any quality control studies in the unit.

## **4. The role of respiratory care protocols in neonates**

One way of harmonizing practices is through the use of respiratory care protocols. Protocols are a set of guidelines or rules to follow for a prespecified population with a prespecified condition. They have been extensively studied in critically ill adult and pediatric patients, namely for sepsis, sedation, hyperglycemia and MV. In these patients, MV protocols have consistently been demonstrated to improve outcomes by reducing costs, decreasing MV duration and shortening length of stay [62, 63]. They also have been shown to reduce rates of extubation failure as well as unplanned extubations [64, 65]. As such, MV protocols have been considered standard of care and have been developed and implemented by over two-thirds of adult ICUs [66, 67].

In contrast, the evidence for using respiratory care protocols in neonates is still limited. Studies are small, single center and retrospective or observational in nature. In one Canadian study,

the implementation of a respiratory therapist-driven MV protocol for premature infants with birth weight <1250 g resulted in earlier extubation, greater number of successful extubations and shorter duration of MV [68]. In another study, the implementation of a standardized SBT protocol for extubation of extremely preterm infants resulted in faster weaning times with no impact on extubation failure rates [69]. In a further study, the implementation of a nurse-driven comfort protocol in ventilated preterm infants significantly reduced the amount of morphine used which translated in fewer days on MV and a shorter course of hospitalization [70]. Lastly, the use of a standardized surfactant protocol allowed clinicians to audit their practice and identify strategies to reduce adverse events associated with surfactant administration [71]. The results of this quality control initiative led to later modifications of the surfactant protocol, which has recently been published [72].

Despite the lack of strong evidence, it is interesting to observe that many units have already developed and implemented respiratory care protocols. In a recent Canadian survey, we showed that 38% of NICUs had at least one MV protocol, while 29% had a protocol for NIV [16]. In another international survey, 36% of units reported having a guideline or written protocol for ventilator weaning [23]. Protocols for CPAP and NIPPV are available in approximately 20% of units [16, 27, 28], while guidelines for HFNC are present in 25–50% of units [16, 29, 30].

The most striking trend is the increasing use of iNO protocols in practice. With the rising costs of iNO treatment, there have been many incentives from clinical managers and hospital administrators to audit iNO practices within their respective units. As a result, it is no surprise that almost two-thirds of units have developed and implemented iNO protocols [16]. To our knowledge, there have been no studies directly evaluating the impact of implementing iNO protocols in neonates, but there is some evidence from the pediatric literature that iNO protocols reduce practice variability, decrease iNO usage and thus lower costs without affecting mortality [73, 74]. As such, several local, national and international committees have published evidence-based guidelines to assist NICUs in developing their own institutional protocol.

Finally, there is a rising body of evidence recommending the development and implementation of clinical protocols for other specific neonatal practices or conditions. Some of these include pain control, sedation, feeding and delivery room management of extremely preterm infants (i.e., the golden hour) [75–77]. But the area in which protocols have been most well studied remains the respiratory management of neonates with congenital diaphragmatic hernia (CDH). In this population, implementation of a standardized, evidence-based protocol for respiratory care (e.g., using gentle ventilatory approaches, and permissive hypercapnia) has reliably led to lesser practice variations, improved survival and decreased morbidities [78–80].

## 5. Development and implementation of respiratory care protocols in the NICU

From the above sections, there is no doubt that respiratory care protocols confer many benefits. But, under some circumstances, they may also have some disadvantages (**Box 2**). Developing and implementing a respiratory care protocol is not an easy task. It requires mobilization of many collaborators, careful scrutiny of a large body of evidence and ongoing monitoring to ensure adequate application of the protocol in practice. This section will outline the key principles for effectively developing and implementing respiratory care protocols in clinical practice (also summarized in **Box 3**).

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### Box 2.

Pros and cons of respiratory care protocols.

#### Pros

- Reduces unnecessary variability in care
- Quick adoption of new information at the bedside
- Educational aids for trainees and allied health care team
- Improves communication
- Decreases costs
- Decreases errors
- Improves patient safety

#### Cons

- Inappropriately used for certain patients or conditions
  - Oversimplified or too prescriptive
  - Designed around low-quality evidence
  - Potential loss of individualization of care
  - Potential to be outdated if not kept current
- 
- 

### Box 3.

General principles for effectively developing and implementing respiratory care protocols.

### **Preconception**

- Obtain support from all team members
- Form a multidisciplinary working group
- Take into account that developing and implementing protocols require ample time, organization and resources

### **Development**

- Easy to use
- Patient and disease specific
- Not too prescriptive
- Does not replace clinical judgment

### **Implementation**

- Readily available
- Regular educational sessions
- Regular monitoring of adherence and compliance
- Periodical revision to accommodate for new evidence or clinical practice patterns

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## **5.1. Preconception**

Well before any protocol is drafted, it is important to take the time to get buy-in from all members of the team who will eventually be using the protocol. This includes nurses, nurse practitioners, respiratory therapists, neonatologists and their respective professional leadership. Many providers are often unaware of the negative impacts of variability on health care outcomes. Others may feel skeptical about the benefits of protocols, potentially fearing that it will take away from their ability to individualize patient care. Thus, it is of utmost importance to provide a clear rationale for using a certain protocol in the unit. Showing unit-specific data that highlight practice variations and compare outcomes with other centers may be a useful step to further justify the need for a protocol. Thus, by involving all stakeholders as early as the preconception phase, all team members will feel included and invested in the realization of the project. This will further aid in improving later rates of adherence and compliance to the protocol.

Once buy-in is obtained, the next crucial step is to create a working group that will be in charge of preparing the protocol. A member from each discipline involved in providing respiratory care (e.g., neonatologist, respiratory therapist, nurse, pharmacist and respirologist) should be encouraged to participate in this group. By using such approach, all key disciplines are represented and given the opportunity to share their perspectives. This multidisciplinary

endeavor should lead to a stronger, more comprehensive and especially more inclusive protocol.

## **5.2. Preparation of the protocol**

The development of a sound protocol depends heavily on the accuracy of its content. If a protocol is based on outdated or low quality evidence, it may actually lead to undesirable or even harmful effects. For that reason, it is essential to perform a thorough review looking for the best available evidence in the literature. Ideally, protocols should be based on results from randomized controlled trials, systematic reviews and meta-analysis. In the absence of such high-quality evidence, other studies should be carefully scrutinized with a critical mind. Additional information should be sought out from expert opinion or from other units who already have had some experience with that specific protocol. Furthermore, epidemiological databases can be a useful resource to identify centers that have better outcomes in a certain aspect of respiratory care and collaborate with them in order to identify potentially better practices responsible for these positive outcomes.

With regard to the information contained in the protocol, it should preferably be patient specific, disease specific and easy to follow. A protocol that is too flexible or unclear may lead to variable interpretations and misuses. In contrast, a protocol that is too rigid, detailed or overly specific may become inapplicable for most patients. Thus, careful attention should be placed on developing a protocol that englobes most targeted patients but that also leaves some room for individualized decision making.

## **5.3. Implementation and monitoring**

Once the protocol is completed and approved by the necessary regulatory authorities, a number of steps need to be undertaken in order to ensure its adequate implementation. First, the protocol needs to be made readily available to all health care providers who will use it. Different channels can be used to disseminate the protocol, including the hospital intranet, monthly newsletters, posters in the unit, printed copies at the bedside and small laminated cards for staff to carry. Second, the protocol should be formally presented at educational sessions, in-services and special rounds with the aim to raise awareness, answer people's questions and clarify their concerns.

Following implementation, an effort should be made to monitor adherence to the protocol in an ongoing manner. In the absence of monitoring, it is not uncommon for protocol compliance rates to decrease with time. Thus, it is important to regularly monitor protocol usage in the unit in order to identify any major issues and promptly correct them. Regular refresher sessions may also be useful to reinforce the protocol. Finally, it is plausible that with time, new evidence-based recommendations will be made available, and hence the protocol might become outdated. As such, protocols should be revised periodically and resubmitted for approval.



## 6. Conclusion

Neonatal respiratory care involves prompt lung recruitment and adequate ventilation and oxygenation during the transition period immediately after birth to management of a variety of respiratory conditions. For this, a number of different technologies and adjunctive therapies are available with lack of high-level evidence for several of them. Thus, it is not surprising that practice variability is a reality. Respiratory care protocols are an attractive tool to promote practice standardization and reduce unnecessary variations and health care-related costs. Despite the limited evidence supporting their use in neonates, a significant number of NICUs have already developed and implemented clinical protocols into practice. Overall, respiratory care protocols appear to promote evidence-based practices, discourage outdated approaches and ultimately improve patient safety.

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