

# HealthTech Report

## Neonatal Airway Interface Devices

A landscape review

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## Contents

Acronyms	iv
1. Introduction	1
2. Respiratory support devices	2
3. Neonatal airway interfaces	3
3.1 Head and oronasal interfaces	3
Oxygen hoods	3
Face masks	3
3.2 Supraglottic airway interfaces	6
Overview	6
Laryngeal mask airways	7
3.3 Infraglottic airway interfaces	8
3.4 Nasal interfaces	9
Overview	9
Nasal masks	10
Nasal prongs	10
Nasopharyngeal catheters	11
4. Discussion	12
4.1 Brainstorming session at PATH on opportunities for innovation	14
For use during neonatal resuscitation	14
For use during CPAP	16
4.2 Resuscitation	17
4.3 CPAP	18
5. Conclusions	19
5.1 Resuscitation	19
5.2 CPAP	19
References	20

## Acronyms

BiPAP	bilevel positive airway pressure
CPAP	continuous positive airway pressure
EGTA	esophageal gastric tube airways
EOAs	esophageal obturator airways
ET	endotracheal
LMAs	laryngeal mask airways
LRS	low-resource settings
PEEP	positive end expiratory pressure
PIP	peak inspiratory pressure
RDS	respiratory distress syndrome
SNP	single nasal prong

## 1. Introduction

Neonatal airway interfaces are used in a variety of applications, including mechanical ventilation, delivery of anesthetic gases during surgery, oxygen therapy for treatment of pneumonia, delivery of liquid (bolus) or nebulized surfactant, delivery of other nebulized drugs such as antibiotics, continuous positive airway pressure (CPAP), bilevel positive airway pressure (BiPAP), and resuscitation. Each application has particular requirements, constraints, and challenges associated with the airway interface, so different types of airway interfaces have been developed in an attempt to meet the particular needs of each. Factors that influence the type of airway interface used include patient age, patient specifications (such as lung compliance), airway resistance, facial structure, health conditions, and the skill of the operator.

The primary function of an airway interface is to facilitate the efficient delivery of respiratory gases to and from the distal airway. For most applications, reduction of leak from the airway interface is an important performance characteristic. For any kind of positive pressure ventilation, such as mechanical ventilation, CPAP, or resuscitation, it is important to keep interface leak to a minimum in order that the target tidal volume and airway pressure may be achieved. For treatments that span more than a few hours, a well-fitted airway interface is critical to avoid injury at the point of contact. A relatively leak-free airway interface also increases the volume fraction of inspired oxygen that is possible to deliver, as well as offering the practitioner more precise control of this important parameter. Finally, oxygen is a scarce commodity in low-resource settings (LRS), so leak reduction allows for preservation of this precious and life-saving drug.

Other performance characteristics also play a role. For delivery of nebulized drugs—particularly for relatively expensive drugs such as surfactant, low dead-space reduces wastage. Neonates that are unconscious require airway interfaces that provide a degree of splinting to reduce the risk of upper-airway obstruction due to relaxation of the tongue and soft tissues. Depending on the design, some airway interfaces afford a degree of protection against aspiration of stomach contents, either by blocking or bypassing the esophageal opening.

Connections to the interface are varied. Typically, an ISO standard 15 mm or 22 mm conical fitting is used for masks while cannula generally employ elastomeric fittings designed to be pushed onto barbs, although this is not a hard and fast rule. For all applications except manual resuscitation, tubing is required to connect the interface with the source of gas, and this tube is also varied in style. Large-bore tubing is designed to minimize resistance to flow, and is ubiquitously used for mechanical ventilation. Smaller-bore oxygen tubing, on the other hand, is the standard for oxygen therapy as it is less bulky and flow resistance is less of a concern. CPAP therapy uses either kind of tubing, and in the case of improvised CPAP, either can be used. Some tubing incorporates heated wires that are designed to prevent ‘rainout’, the condensation of water that results when humidified, warmed gas comes into contact with the tubing wall. Condensation is not only dangerous as a result of the risk of aspiration by the neonate, but it also promotes microbial growth in the respiratory circuit.

Given current global efforts to decrease neonatal mortality through proven lifesaving interventions in LRS, the purpose of this report is twofold: 1) to provide an overview of existing neonatal airway interface devices that can be used for either neonatal resuscitation or administration of CPAP, and 2) to identify promising innovations and concepts that have the potential to be further developed or more widely used in LRS. Information contained within this report is the result of a literature search, review of

relevant manufacturer websites, and a PATH innovation brainstorming session. Airway interfaces that are not suitable for neonates such as esophageal obturator airways or esophageal gastric tube airways or those designed to be used after surgical procedures such as tracheostomy were not included in this scope of work.

## 2. Respiratory support devices



*Figure 1. From left to right: T-piece (Photo: University of Washington/Dr. Meenakshi Dutta); self-inflating resuscitator (Photo: University of Washington/Dr. Meenakshi Dutta); flow-inflating resuscitator (Photo: PATH/Greg Kachmarik).*

There are three general types of manual devices that are used for neonatal resuscitation: T-piece devices, self-inflating bag devices, and flow-inflating bag devices (Figure 1). These devices can be coupled with either invasive or noninvasive interfaces.

T-pieces such as the Neopuff™, NeoPIP™, and similar devices have become popular in delivery rooms of high-resource settings. They require a compressed gas source and are designed to deliver consistent peak inspiratory pressure (PIP) and positive end expiratory pressure (PEEP) that can be set and adjusted by the operator. T-pieces can be used to provide positive pressure resuscitation via a face mask, endotracheal (ET) tube, or nasopharyngeal tube. An audible soft “whistle” is heard and the preset PEEP is displayed on a manometer when the operator has achieved a good face-mask seal. These signs are not seen or heard if there is a leak between the mask and the infant’s face.

Self-inflating bag devices are not dependent on a gas source to function. These devices are portable, lightweight, and available in single- and multi-use varieties. When using a self-inflating bag with a face mask, operators check for chest rise to determine a good face-mask seal.

Flow-inflating bag devices will only inflate when compressed gas is flowing into the bag and the patient outlet is occluded.

CPAP therapy requires a source of pressurized gas (generally a blend of air and oxygen). There are several means of generating pressure: a dedicated CPAP device uses a compressor to deliver compressed air, which can then be blended with pressurized oxygen from a tank, facility wall supply, or oxygen concentrator; ventilators also commonly have a CPAP mode that provides blended gas; or a bubble CPAP device that relies upon a column of water for pressure generation and control.

### 3. Neonatal airway interfaces

#### 3.1 Head and oronasal interfaces

##### *Oxygen hoods*



*Figure 2. An example of an oxygen hood. This particular hood, the Disposa-Hood™ from Utah Medical Products Inc® ([www.utahmed.com](http://www.utahmed.com)) is designed to be disposable. The oxygen port is visible on the far left of the photograph and a port that allows for humidification is located on top of the hood. Photo copyright of Utah Medical Products.*

An oxygen hood (or head box) works by entirely enclosing an infant's head in a transparent box that is connected to an oxygen supply. Oxygen is provided at a rate sufficient to ensure that expired gases are not rebreathed, usually 6 liters per minute or more. Oxygen hoods are most suitable for oxygen therapy where a seal is not required to generate pressure, but simply an adequate supply of oxygen. Expired gases are flushed through the opening around the neck or upper chest. Oxygen hoods are not suited for neonatal resuscitation and are not particularly suited for CPAP as the opening must be sealed by means of a rubber flap around the neck of the infant in order to maintain positive pressure. This seal is easily breached during movement of the infant and additionally limits access to the neonate's face for suctioning and feeding.

##### **Face masks**

Face masks come in a wide variety of styles, depending on their intended use. Generally, masks are designed to cover both the nose and mouth and allow the regulated flow of gas over the face. Masks intended to transmit pressure to the patient—as is the case for resuscitation and CPAP—must maintain a good seal, whereas those that are intended to provide supplemental oxygen do not need to do so. For prolonged respiratory support, face masks are held in place with an elastic strap around the patient's head.

## Bag-valve masks



*Figure 2. Bag-valve masks in different sizes. The masks at the top of the image show anatomically shaped masks with rigid mask covers designed to minimized distortion. Photo copyright of Laerdal Medical.*

Bag-valve masks (otherwise known as oronasal masks) are designed to cover both the nose and mouth with a good seal maintained by simple application of hand pressure (Figure 3). They are typically made from silicone, a transparent and compliant material that can conform to the contours of the face as well as allow a modicum of visibility into the mouth and nose. Silicone masks are also durable and are able to be stored and reused many times if appropriate disinfection procedures are followed.

As their name implies, bag-valve masks are intended for use with self-inflating resuscitators, attached by means of a standard ISO 15 mm conical connector. Higher levels of oxygen can be delivered through bag-valve masks, although the non-rebreathing valves are typically located on the resuscitator itself, rather than being incorporated into the mask as is the case in non-rebreathing masks.

Bag-valve masks designed for infants are typically round, but are also available in shapes that are contoured to match the anatomy of the face. These latter style of masks, however, assume a generic facial shape and studies have shown no statistically significant variation in efficacy between mask types.<sup>1</sup> Anatomically-shaped masks have not been proven to be any more effective than round-shaped masks. A survey of 46 hospitals in 23 countries was conducted to determine the use of neonatal resuscitation devices and masks by type. In the neonatal intensive care units, 85 percent used round-shaped face masks and 15 percent used anatomically-shaped face masks. About 28 percent of the hospitals used a mixture of the two types of masks.<sup>2</sup>

Overall, bag-valve masks are preferred for resuscitation over nasal masks or nasal prongs because they obviate leak through the mouth and the increased contact area around the face seal allows them to withstand much higher pressures. The skin contact surface of a bag-valve mask (the mask lip) is generally of a much thinner wall, and is often shaped like the skirt of a hovercraft in order to maintain

the best possible seal. Some bag-valve masks have an inflatable lip that is intended to enhance the ability of the mask to conform to the anatomy of the face.

The manner in which the bag-valve mask is placed and secured on the infant's face is important in optimizing the seal and minimizing leak. Insufficient pressure or incorrect positioning over the nose and mouth will result in leak, but this can also occur if the bag-valve mask is squeezed too hard, causing distortion and breaching of the seal against the face. Some bag-valve masks are designed to be thicker and more rigid—except at the lip—in order to minimize distortion. Rigid mask covers are another means of reducing mask distortion while still maintaining a compliant interface against the face. Mask covers are typically made from plastic and often feature eyelets for attaching elastic straps if needed. When properly used, a bag-valve mask can provide an extremely good seal, but inadequate training and infrequent use often result in the presence of significant leak and poor outcomes.

Bag-valve masks are available in several sizes for use with premature infants to small children and adults, although self-inflating resuscitators are often sold with only a single mask size. If an adequate supply of masks in various sizes is not purchased, practitioners may find proper mask fitting and effective ventilation more difficult or impossible to achieve.

#### Pediatric pocket masks



*Figure 3. Pediatric pocket mask by Laerdal Medical. Photo copyright of Laerdal Medical.*

Pocket masks, also referred to as CPR masks, are small devices which closely resemble bag-valve masks, but with the addition of a mouth port that may contain a one-way valve and a filter. The person resuscitating the infant breathes into this port to supply gas to the baby. The valve and filter are designed to prevent viral and bacterial transfer between the resuscitator and patient. Appropriate technique adaptations are required to avoid blowback from the patient.

Pocket masks are not the standard of care for neonatal resuscitation. However, a study reported an intervention that included successful use of the pocket mask by traditional birth attendants in low-resource settings, which contributed to decreasing neonatal mortality in the study site.<sup>3</sup> The mask and port are designed to be tall enough to allow the resuscitator to simultaneously ventilate the infant and watch for chest rise. The pocket mask requires only one hand to both form a seal and to supply breaths.

This leaves the second hand free to hold the patient's head to keep the trachea from collapsing. These devices are generally disposable or single-use and can be transported easily inside a clamshell case.

### Simple face masks

Simple face masks are vented masks that cover the nose and mouth and are intended for the delivery of low-volume fractions of supplemental oxygen when there is no requirement for precise control. Delivery of high-volume fractions of oxygen are not possible due to the relatively high dead space of the mask and the rebreathing of end expiratory gases. Exhalation vents in the sides of the mask permit the flow of exhaled gases into the atmosphere and dilute the inflow of oxygen during inhalation. The presence of the vents precludes the use of this type of mask for CPAP or resuscitation.

### Non-rebreathing and partial-rebreathing masks

Non-rebreathing masks are similar to simple face masks except that one-way valves are incorporated in place of the vents, ensuring the infant does not inhale room air or rebreathe exhaled air when supplemental oxygen is used. The purpose is to provide a higher fraction of delivered oxygen than would otherwise be possible. A reservoir bag is used in conjunction with the mask in order to ensure the infant is able to draw sufficient oxygen during inhalation (i.e., peak inspiratory flow), while maintaining an oxygen flow-rate that is only slightly in excess of the infant's minute ventilation.

A partial-rebreathing mask is similar to a non-rebreathing mask without the valves and the reservoir bag is partially inflated. This permits the first third of the exhaled tidal volume to be returned to the reservoir bag, while the remaining exhaled gas flows out through open ports in the mask. As the first third of the exhaled gas comes from the anatomic dead-space, it has a relatively unchanged volume fraction of oxygen and carbon dioxide and volume fractions of oxygen as high as 60 percent can be delivered. Partial-rebreathing masks are generally not used for CPAP or resuscitation.

## **3.2 Supraglottic airway interfaces**

### ***Overview***

This section describes orally inserted devices that terminate superior to the larynx. These devices can generally be placed without direct visualization and, with a couple of exceptions, provide little protection against pulmonary aspiration. These devices are therefore not recommended when aspiration is determined to be a significant risk or if the patient is conscious as the airway will stimulate the gag reflex. Various types of supraglottic airways are available, ranging from appropriately sized and shaped tubes to more complex devices designed to fit directly over the larynx.

## Laryngeal mask airways

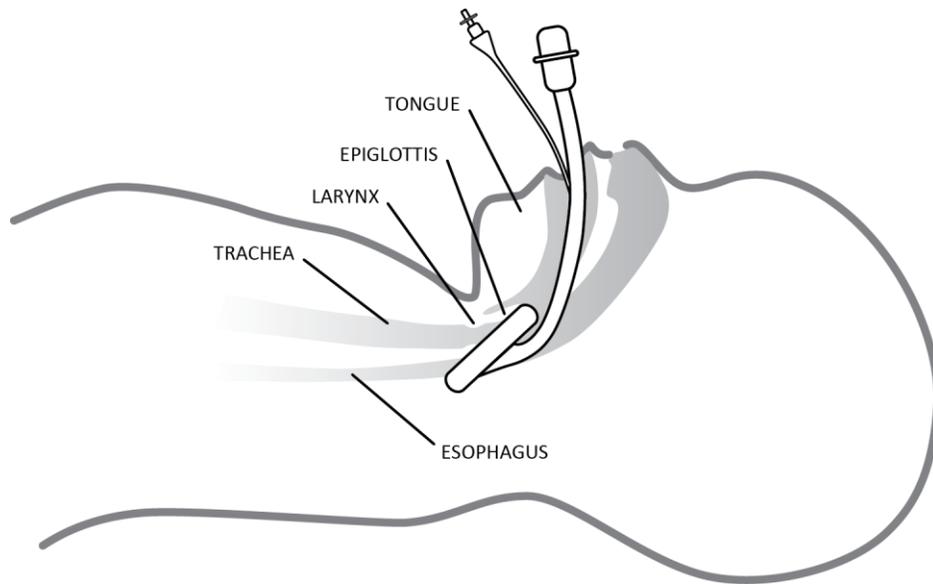


Figure 5. A diagram showing a laryngeal mask airway. The device is designed to fit superior to the larynx, covering the trachea and blocking access to the esophagus. Once the mask is in position, an inflatable cuff secures the device and seals the airway.

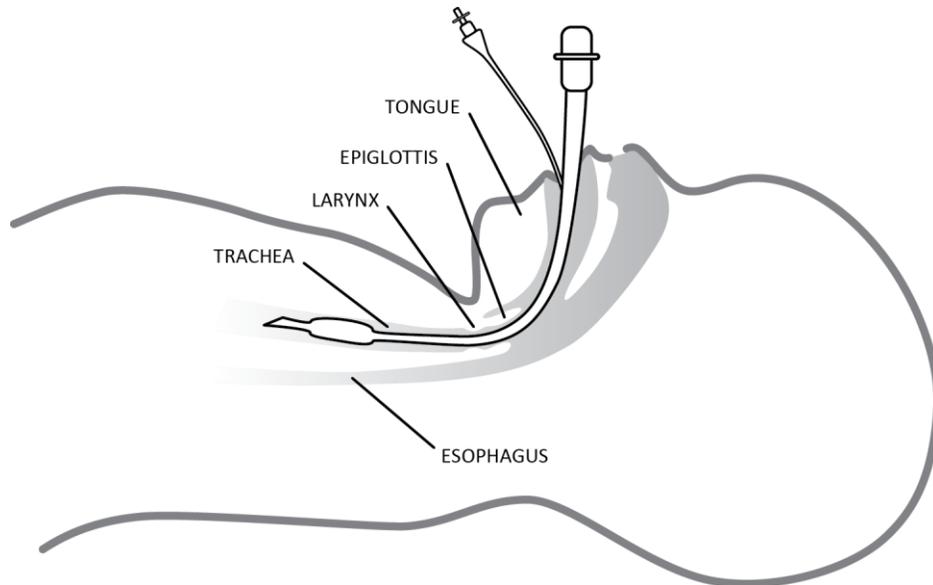
Laryngeal mask airways (LMAs) are supraglottic airway devices that can be used for both resuscitation and positive pressure ventilation up to 20 centimeters of water depending on the specific device that is used.<sup>4</sup> The device is inserted into the lower oropharynx using the index finger and positioned over the laryngeal opening so that the tip sits in the upper esophagus (see Figure 5). Once in position, the mask is inflated to provide a seal over the laryngeal opening, avoiding challenges associated with face-mask seal. Care must be taken not to overinflate, as this may result in a more rigid mask that is less able to conform to the anatomy of the airway. Similar to an endotracheal (ET) tube, the LMA prevents obstruction of the airway by the soft tissue and is used as the standard technique for ventilation if ET intubation cannot be accomplished or is not permitted. Prolonged placement or overinflation, however, may compress the tongue and cause edema, so LMAs are not recommended for extended use. Other complications include vomiting and aspiration with infants who have an intact gag reflex or who are receiving excessive ventilation.

Placement of an LMA does not typically require the use of a laryngoscope, greatly reducing the skill, time, and risk associated with establishment of an airway with an ET tube. Laryngoscopes require training to operate safely, and drugs are required prior to placement of an ET tube in conscious patients to relax the muscles of the upper airway, provide sedation, and reduce pain. In contrast to ET intubation, LMAs are placed proximal to the larynx so there is significantly less risk of trauma to the vocal cords and other laryngeal structures.

Although LMAs do not isolate the airway from the esophagus as effectively as ET tubes, they do provide some degree of protection against passive regurgitation and reduce the amount of air that is introduced to the stomach. This risk is further mitigated in some more recent LMA designs that allow passage of a gastric tube to permit decompression of the stomach, although care must be taken to ensure that the LMA is properly positioned. Another recent innovation in LMA designs is the use of a gel mask that molds to the airway without requiring inflation. This helps to reduce the risk of leak due to mask over-

inflation, and reduces both the number of user steps and the overall complexity of the device. Some LMAs are designed to be sterilizable and have the potential to be reused up to 40 times.<sup>5</sup>

### 3.3 Infraglottic airway interfaces



*Figure 6. A diagram showing an endotracheal tube inserted into the trachea. An inflatable cuff secures the device inferior to the larynx. Often, a nasogastric tube (not shown) is inserted into the esophagus to clear stomach contents.*

This section describes ET tubes, orally inserted devices that terminate below the larynx. ET intubation is used during neonatal resuscitation under specific circumstances (ineffective or prolonged bag-mask ventilation, tracheal suctioning of meconium required, etc.). ET tubes are relatively large-bore tubes that are inserted directly into the trachea through either the mouth (Figure 6) or, less commonly, the nose. Placement of an ET tube typically requires the aid of a laryngoscope to retract the tongue and epiglottis and visualize the tip of the ET tube as it passes through the delicate vocal folds of the larynx. As a result, this procedure is relatively complex when compared with application of other neonatal airway interfaces and practitioners must therefore have a high degree of skill, training, and experience.

Most ET tubes feature an inflatable cuff that is used to secure the airway within the trachea, serving both to prevent leaks and minimize the possibility of aspiration. Cuffed tubes have traditionally only been used in adults and children over eight years of age; however, use in infants is becoming more widespread, particularly during transport to prevent leaks. Uncuffed tubes are usually used during neonatal resuscitation. After the ET tube has been placed, the proximal end is connected to the respiratory circuit or ventilation bag and secured with surgical tape or a head strap designed for this purpose.

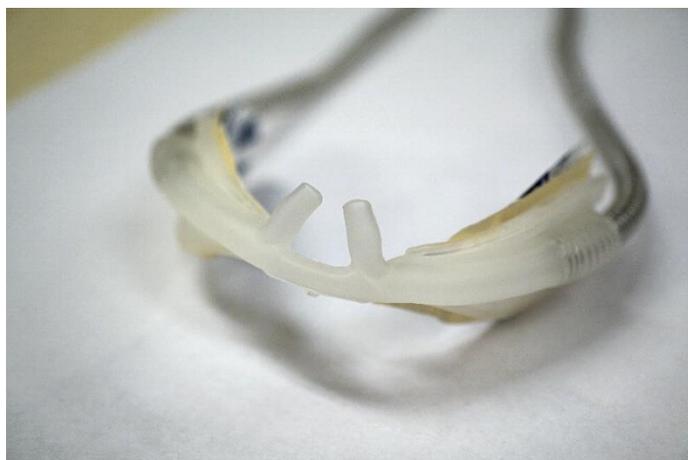
For resuscitation, ET intubation is usually only attempted if mask ventilation fails and adequate ventilation cannot be achieved. For infants with respiratory distress syndrome (RDS), or for infants born extremely prematurely, a bolus of exogenous surfactant can be administered to the lungs using the INSURE method—an intubation, surfactant, extubation sequence. This is the most commonly used method for the instillation of bolus surfactant to preterm infants for the treatment of RDS, particularly in settings where training, equipment, and surfactant are not in short supply.<sup>6</sup> ET intubation is also

chosen when intratracheal epinephrine must be administered and when meconium must be suctioned from the airway or when resuscitation is prolonged.<sup>7</sup>

Tracheal intubation is considered an invasive procedure that carries risks of its own. Insertion of the tube into the trachea may cause trauma to the upper airway including damage to the larynx, perforation of the esophagus, obstruction of the trachea, right main bronchus intubation, and accidental extubation. It is also important that intubation is successful on the first attempt as successive attempts at laryngoscopy have been associated with significantly higher rates of hypoxemia, aspiration, and cardiac arrest.<sup>8</sup> Administration of a bolus of surfactant through the ET tube also poses risks, including bradycardia, transient hypoxia, hypotension, and reduced cerebral blood flow.<sup>9</sup> Further, prolonged intubation can irritate the airway, causing chronic injury.

### 3.4 Nasal interfaces

#### Overview



*Figure 7. Fisher & Paykel's Optiflow™ Junior Nasal prongs and Wigglepads™. Photo: PATH/ Alec Wollen.*

Nasal interfaces are designed to deliver oxygen, positive airway pressure, or both to the lungs of a patient. Nasal interfaces are generally designed to be inserted into one or both nares, with the exception of the nasal mask which, as the name implies, is a small mask designed to cover just the nose. Ventilation of gases during exhalation is dependent on whether the mouth is held closed.

Heating and humidification of respiratory gases is an important factor to consider when providing respiratory therapy of any kind. Nasal delivery of respiratory gases partially compensates for the issue of dry and/or cold gases as the nose performs these functions itself. Prolonged treatment, high flows, or sick infants, however, will negate the ability of the nose to compensate, so these issues are generally addressed in the respiratory circuit by providing heated, humidified gas. The interface itself, however, is generally not heated, so if the length of the interface tubing is long, then condensation or 'rainout' can occur, potentially occluding the airway and encouraging microbial growth.

Fixation of a nasal interface is achieved by a number of methods, the crudest being the use of surgical tape to secure tubing to the infant's cheeks. Bonnets and head-straps are commonly utilized with safety pins or specially designed clips to hold the airway interface and respiratory circuit in place. Fisher & Paykel Healthcare has developed an innovative pad (Wigglepads™) integrated into their Optiflow™

Junior prongs (see Figure 7) that adhere to the infant's cheeks while permitting temporary removal of the prongs via a Velcro® layer.

### **Nasal masks**



*Figure 8. The Fisher & Paykel silicone nasal mask designed to fit to their proprietary FlexiTrunk™ Midline Circuit. The mask is available in four sizes. Photo: PATH/ Alec Wollen.*

Nasal masks cover the nose and nares of the infant, with a seal maintained against the face. The primary advantage of nasal masks over interfaces that encroach on the nares is that the risk of trauma to the nasal septum and nasopharynx is obviated. Nasal masks must be sized so that no part of the mask touches the eyes, nose, and lips, and the nares are not occluded. Elastic straps affixed around the infant's head typically hold the nasal mask in place. Some nasal masks are known to cause irritation to the bridge of the nose to form a tight seal. Recent modifications have been made to the design of nasal masks to increase comfort and to achieve a better seal, including use of gels on the contact surface of the mask. This device is used for CPAP and is not currently used for resuscitation.

### **Nasal prongs**



*Figure 9. An example of various sizes of short binasal prongs manufactured by Fisher & Paykel, designed to fit their proprietary Flexitrunk Midline Circuit (not shown). These prongs are available in 11 sizes, ranging from internal prong diameters of 3.0 mm to 6.5 mm, and prong separation distances from 2 mm to 7 mm. Photo: Alec Wollen.*

Nasal prongs come in a variety of styles, but typically refer to nasal interfaces with two prongs (binasal prongs), one for each nare. Short binasal prongs (shown in Figure 9) are the most widely used nasal interface, particularly for oxygen therapy and administration of CPAP. Prong length varies, but typically short binasal prongs are between 6 mm (in the case of the smallest Argyle prong) and 15 mm (largest Hudson prong) in length. Longer lengths generate more resistance than shorter lengths but are less prone to leak around the nares.

Aside from length, prong lumen diameter and separation distance are critical to both performance and safety. Lumen diameter has a disproportionate impact on flow resistance in comparison to prong length—halving the internal radius increases the resistance to flow by the fourth power. This is of particular importance for CPAP, where the generation of pressure in the airways and lung is the primary mode of action. In addition, a small lumen is more prone to clogging and, therefore, frequent inspection and clearing of the lumen are necessary.

The external diameter of the prong impacts the degree of leak experienced at the nasal interface. For oxygen therapy requiring low-volume fractions of oxygen, this is not critical, and entrainment of room air is, in fact, necessary for low-flow therapy where the oxygen provided does not meet the minute ventilation requirements of the neonate. For CPAP, however, a good seal is important in order that leak is minimized so that pressure may be transmitted to the lung.

Many nasal prongs come with transparent sizing templates, helpful for selection of the optimal size of nasal interface. The goal in sizing for CPAP is to fill the nares entirely, but without contact or pressure on the surrounding tissue, including the nasal septum. For oxygen therapy, the goal is to fill about half the area of the nares. Correct prong separation ensures that the nasal septum is not compressed. Incorrect sizing, prolonged use, or infrequent cleaning can lead to trauma, including erosion of the nasal septum.

Short binasal prongs have been developed in a wide variety of geometries, mainly intended to mitigate issues of leak, trauma to the nose, resistance to flow, or large dead space. Examples of innovations include flared prongs (Hudson), curved prongs for a better anatomical fit, cutaways to avoid contact with the nasal septum (Fisher & Paykel), and flow reservoirs.

### ***Nasopharyngeal catheters***



*Figure 10. An example of a nasopharyngeal catheter (also known as a single nasal prongs, nasopharyngeal airway, or nasal trumpet). Photo copyright of PhilipN.*

Nasopharyngeal catheters are nasal interfaces that are usually referred to as single nasal prongs (SNPs). Nasopharyngeal catheters (or prongs) are designed so that the tips are positioned in the nasopharynx, rather than at the nares, and they are typically 40 mm or longer.

Nasopharyngeal catheters (otherwise known as SNPs, nasopharyngeal airways, or nasal trumpets) are available commercially (see Figure 10), but in clinical settings are often devised from ET tubes of an appropriate size that have been cut to length, lubricated, and inserted so the tip is positioned in the nasopharynx. The device is secured by means of an inflatable cuff (a component of the ET catheter) or with tape over the bridge of the nose and wrapped around the proximal end of the catheter. Purpose-made devices (nasopharyngeal airways) come in a variety of sizes, are curved with a beveled tip, and are designed to be inserted in the largest nare with the curve in the direction of the oral cavity. The proximal end is flared to prevent the device from slipping entirely into the nasal cavity. Sizing is accomplished in the same manner as an oropharyngeal catheter: by direct measurement against the patient. The distal tip of the device should align with the angle of the jaw or ear lobe when the proximal end is positioned at the nare. Lengths are typically 40 mm or longer. One advantage of a catheter is the ability to use the other nare for placement of a feeding tube.

In addition to nasal CPAP, SNPs are being explored for use with manual ventilation devices. SNPs provide a strong seal against gas leakage. A recent study has demonstrated that the use of a SNP for neonatal resuscitation is equally as effective as resuscitation via a face mask.<sup>10</sup>

#### 4. Discussion

Table 1 summarizes current advantages and disadvantages of all the airway interfaces described in this landscape, as they apply to use in neonatal resuscitation and CPAP.

Table 1. A summary table comparing neonatal airway interfaces.

<i>Device</i>	<i>Interface type</i>	<i>Suitability</i>	<i>Advantages</i>	<i>Limitations</i>
Oxygen hood; head box	Head	Oxygen therapy	No possibility of facial injury; interface is independent of facial anatomy.	Seal cannot be achieved (not suitable for resuscitation or continuous positive airway pressure [CPAP]).
Bag-valve mask	Oronasal	Resuscitation	Simple and intuitive to use; low cost; easy to clean; for CPAP, less resistance.	Mask seal highly dependent on user experience; may lead to gastric inflation during prolonged ventilation.

<b>Device</b>	<b>Interface type</b>	<b>Suitability</b>	<b>Advantages</b>	<b>Limitations</b>
Pediatric pocket mask	Oronasal	Resuscitation	Low cost, simple and intuitive to use.	Not designed to be used with manual resuscitators; mask seal highly depended on user experience; may lead to gastric inflation during prolonged ventilation.
Simple face mask	Oronasal	Oxygen therapy	Low cost; simple and intuitive to use.	Not designed to provide seal; obstructs access to face for feeding and suctioning.
Non- or partial-rebreathing mask	Oronasal	Oxygen therapy	Can attain higher levels of delivered oxygen compared with simple face masks.	Not designed to provide seal; obstructs access to face for feeding and suctioning.
Laryngeal mask airway	Oral (supraglottic)	Resuscitation	No additional equipment required for placement; may minimize gastric inflation during prolonged ventilation; prevents pulmonary aspiration; requires relatively less training compared to endotracheal tube.	Invasive; requires training; proper insertion dependent on user experience; due to neonatal anatomy, tendency to become dislodged and compress airway in the neck during bag-mask ventilation; pressures in excess of 20 centimeters of water can cause leak.
Endotracheal tube	Oral (infraglottic)	Resuscitation; mechanical ventilation; bolus delivery of drug	Good airway seal; ability to delivery bolus drugs; protects against airway obstruction and pulmonary aspiration; prevents gastric inflation during prolonged ventilation.	Requires specialized training; proper insertion dependent on user experience; additional equipment required for use; possible damage to larynx.

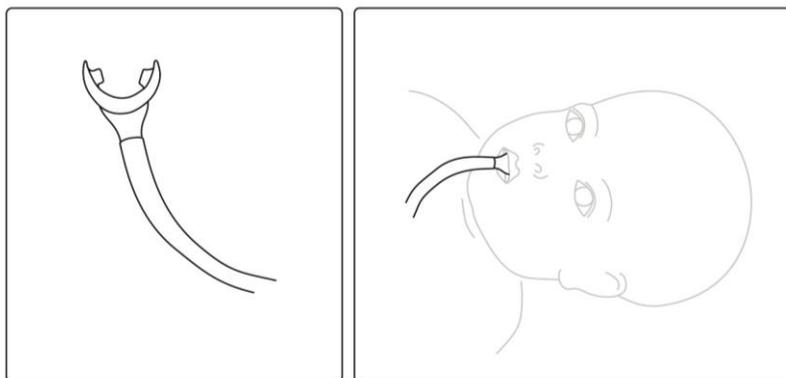
<b>Device</b>	<b>Interface type</b>	<b>Suitability</b>	<b>Advantages</b>	<b>Limitations</b>
Nasal mask	Nasal	CPAP, oxygen therapy	Good airway seal; easy to clean; no risk of septum damage.	Can cause injury to bridge of nose; challenging fixation.
Short binasal prongs	Nasal	CPAP, oxygen therapy	Considered most effective interface for CPAP when compared to single nasal prong. <sup>11</sup>	Can cause tissue damage around the columella and nasal septum; potential fit issues (variable nasal anatomy); challenging fixation.
Single nasal prong, nasopharyngeal airway, nasal trumpet	Nasal (supraglottic)	Resuscitation; heated, humidified, high-flow nasal therapy	Good airway seal; easy to place; other nare is available for nasogastric tube.	Invasive; high resistance; can cause tissue damage around the columella and nasal septum; may lead to gastric inflation during prolonged ventilation; challenging fixation.

#### 4.1 Brainstorming session at PATH on opportunities for innovation

In February 2016, a small team of experts at PATH conducted a brainstorming session to explore possible design concepts that could address some of the key challenges associated with preventing leaks and maintaining pressure in interfaces used for administering resuscitation and CPAP in newborns. Key challenges include securing interface devices in place, establishing a good seal, avoiding injury to the infant’s tissues, and being easy to use by health care providers. The following is a brief overview of some of the concepts that arose during the session which would require further discussion and development.

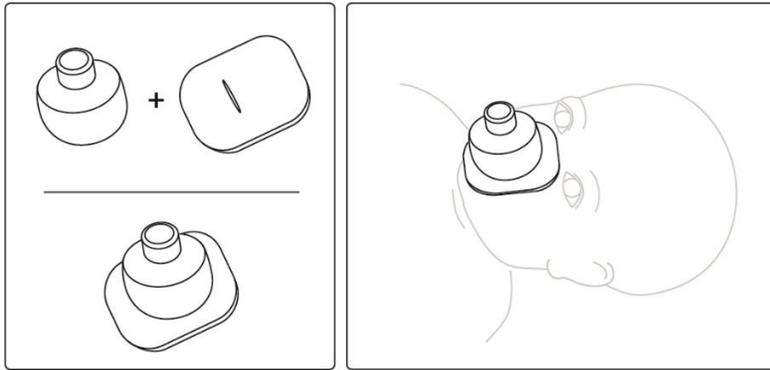
##### ***For use during neonatal resuscitation***

###### Concept 1



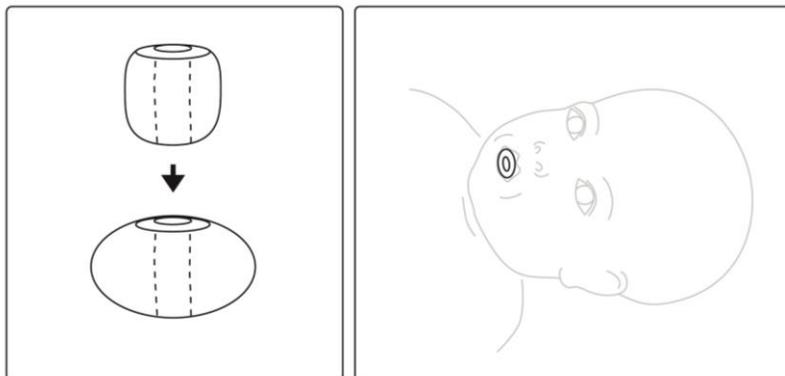
A snorkel-style mouthpiece that establishes a good seal and secures the placement of the mouthpiece. The seal is designed to be between the gums and inside lips of the newborn and improve the robustness of the seal compared to a bag-valve mask. A means of sealing the nose (such as a nose-clip) would have to be devised for this to work.

### Concept 2



A reusable, soft, tacky sheet of silicone-like material with a hole at the mouth for air to go through adheres temporarily to the newborn's face. Existing masks could sit on top, while the sheet provides an improved seal that molds to the newborn's particular facial configuration.

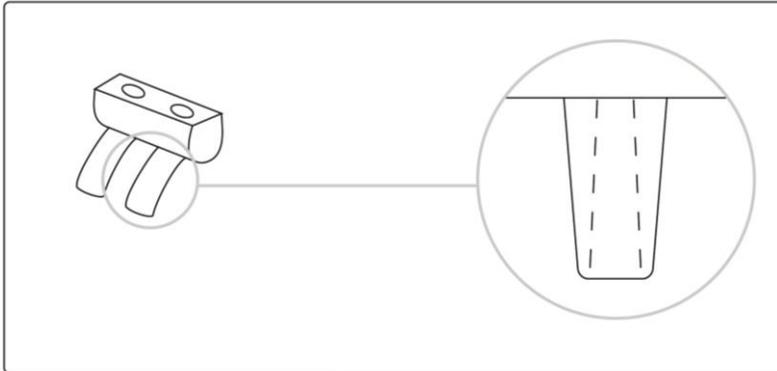
### Concept 3



A rigid tube surrounded by a soft, pliable foam that, once inserted, fills the infant's mouth to provide an easy method of making a securely sealed connection to an air tube. Similar to the snorkel-style mouthpiece, this design is intended to provide a more robust seal, but would require another means of sealing the nose.

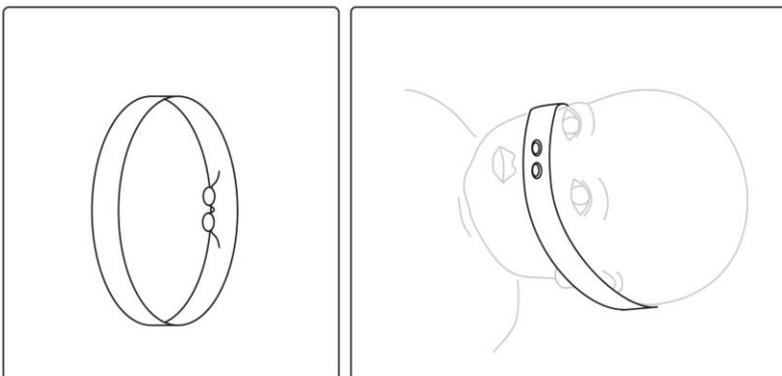
**For use during CPAP**

Concept 4



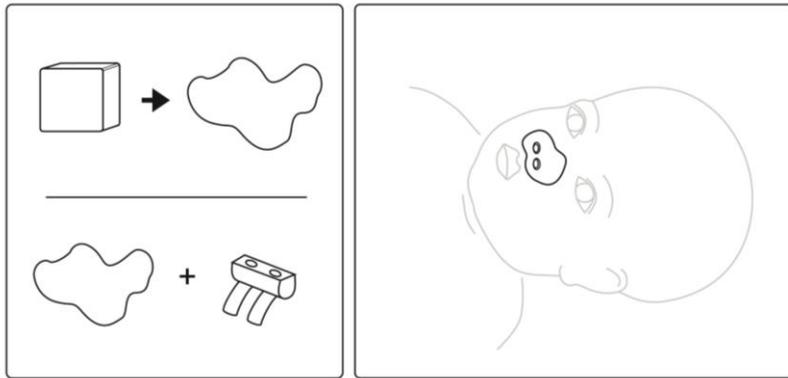
A nasal-prong geometry that has a variable, adjustable wall thickness. A thin section of wall is intended to expand under pressure, filling and sealing the nare with gentle pressure. This concept would both improve seal and reduce the risk of injury to nasal tissue.

Concept 5



A soft, elastic face band that houses nasal prongs to provide a comfortable method for securing a CPAP device. The seal of the face band is designed to be flexible enough to fit a range of prong sizes and, like the sealing sheet described in concept 2, would adhere gently to the face, decreasing damage to nasal tissues.

## Concept 6



A moldable putty that seals around the infant's nose and allows for the secure insertion of nasal prongs to provide a comfortable seal for all types of nares, decreasing damage to nasal tissues.

### 4.2 Resuscitation

For resuscitation, leak reduction is important in order to achieve targeted tidal volumes, but the duration of treatment is much shorter and, consequently, tissue damage is generally less of a concern than is the case for CPAP. Excessive hand pressure exerted on a bag-valve mask, however, has the potential to invoke a vagal response.<sup>12</sup>

LMAs are a potential alternative to oronasal masks for resuscitation and are considered less invasive, easier to introduce, and present a lower risk of trauma to the airway than ET tubes. Incorrect placement of an LMA and laryngospasm are nonetheless possible.<sup>13</sup> A study conducted at Padua University Hospital (Italy) consisting of 18,641 live births demonstrated that resuscitation with an LMA was associated with a lower rate of admission to the neonatal intensive care unit and a shorter length of stay when compared with either bag-mask or ET tube ventilation.<sup>14</sup> In a neonatal resuscitation trial, the LMA was successfully inserted on the first attempt by expert personnel and provided a clinically patent airway that allowed successful resuscitation with no complications directly attributable to its use.<sup>15</sup> LMAs should not be used, however, for bolus delivery of drugs to the lung as success rates have been reported to be low.<sup>16,17</sup>

One study in China evaluated the efficacy of the LMA versus bag and mask for neonatal resuscitation and found that the LMA is safe, effective, and easy to implement for the resuscitation of neonates with a gestational age of 34 or more weeks.<sup>18</sup> LMAs appear to be effective and the method can be easily learned by clinicians with little neonatal-resuscitation experience. Although resuscitation via LMAs is used, the most commonly used interfaces are oronasal masks.<sup>2</sup>

Current methods of establishing and maintaining a secure seal for both oronasal masks and supraglottic airway devices rely heavily on good technique and highlight the need for innovation in this area. Possibilities for such innovation could include taking a fresh look at the means by which masks make contact with the topography of an infant's face. One innovation might be the use of a compliant, tacky material (such as a sheet of silicon) that would fit between a standard mask and the face. This sheet would have a hole in the middle to allow gasses to pass to the airway, the goal being to improve the seal while maintaining compatibility with existing interfaces. A potential feature of such an approach could be visual indication that a proper seal had been achieved by a color change upon pressure.

Other possibilities for novel airway interfaces include different types of mouthpieces that could be placed inside or around an infant's mouth to help keep a tight seal and secure the proper positioning of an airway device. Examples are a rigid-tube connector surrounded by soft, pliable foam that would nest inside the infant's mouth, as well as a silicone-like mouthpiece that rests comfortably in place and covers the lips of the infant in a manner similar to that of a snorkel mouthpiece.

### 4.3 CPAP

One of the main challenges associated with successful CPAP therapy involves achieving a secure airway seal that maintains pressure and prevents leak. A drawback typically associated with nasal CPAP therapy for neonates is the potential for injury of the nasal and surrounding tissue, particularly with prolonged use. Correct sizing, positioning, and fixation of neonatal airway interfaces is critical for both safety and efficacy of treatment. Short binasal prongs are the predominant interface for providing CPAP therapy as they allow access for feeding and suctioning and are relatively easy to place. Neonates, and premature neonates in particular, have delicate skin and mucosa that is easily damaged through abrasion or prolonged or forceful contact. The most commonly reported injuries with the use of binasal prongs can occur at the nares, intranasal septum, columella (anterior tip of the nasal septum), or philtrum as a result of prongs that are too large in diameter; too closely spaced; insufficiently secured, causing movement; or incorrectly positioned, so as to press against the columella.<sup>19</sup> Injury rates between 20 percent and 60 percent have been reported in the literature.<sup>20</sup> A follow-up study by Newnam et al. (2015) concluded that the severity of nasal injury was significantly reduced when a strategy of alternating between nasal mask and short binasal prongs was employed when providing CPAP treatment for extremely low-birthweight neonates.<sup>21</sup>

The use of longer (i.e., nasopharyngeal) prongs may reduce the risk of tissue damage associated with short binasal prongs and is one of the potential benefits of humidified, high-flow nasal cannula therapy.<sup>22,23</sup> This is a result of the reduced requirement for a close fit in order to achieve positive airway pressures and the lack of a second prong reduces pressure on both the nares and columella. Injury is still possible, however, due to the need to remove the prong for suctioning of the nares to clear mucous at regular intervals.

Appropriate sizing of short binasal prongs is also necessary for effective treatment. In low-flow oxygen therapy (i.e., flows not intended to meet the minute ventilation requirements of the neonate), the rule of thumb is to occupy approximately half the diameter of the nares with the cannula for CPAP therapy; the goal is to just barely fill the nares in order to minimize leak but without impingement upon the nasal tissues.<sup>24,25,26</sup>

Potential innovations to improve the range of sizes (both diameter and prong separation) and the means by which the interface is secured on the infant warrant further investigation. Existing interfaces have been designed primarily for the developed markets and are not particularly suited to the larger nares seen in African babies. A gel interface, much like that used for laryngeal masks, may hold promise as a means for creating a gentler, more universal seal. This improved seal could also be achieved with the use of a soft, moldable material that would securely conform directly to the unique physical size and shape of each individual infant's nasal region. For CPAP, this type of seal would be best suited to a nasal mask.

Alternatively, a flexible band of soft, elastic material could form a gentle seal around the nares for securing nasal prongs and wrap around the infant's head to provide a secure positioning of the entire

airway interface device. This type of interface is envisioned to form the connection between the nasal prongs and the face and is intended to reduce the risk of injury to the delicate skin around the newborn nares. A device that fits this description has been developed by the Institute for Pediatric Innovation's Clinical Innovation Catalyst Program and is currently under review by the US Food and Drug Administration.<sup>27</sup>

Other possible innovations for consideration involve updates to the geometry of the nasal prongs themselves. One concept conceived during the brainstorming sessions is a nasal prong that has a thin wall section designed to expand under pressure (see concept 4 above), thereby providing a better seal within the nare itself while reducing irritation and the potential for injury.

## **5. Conclusions**

### **5.1 Resuscitation**

Further innovation in this space is needed to reduce leak, reduce potential for gastric inflation, and improve ease of use of existing interfaces. Currently, the bag-valve mask is the standard for resuscitation, although the LMA has been used more recently outside of the operating room with success. The LMA has the advantage of reducing the amount of gastric distention (thereby reducing the risk of aspiration) and is also a 'hands-free' interface, allowing the practitioner to focus their attention on providing the appropriate tidal volumes and less time worrying about leak. It has been reported to be quick and easy to place by healthcare workers, although we are not aware of any studies that have been conducted in LRS. However, there is a lack of availability of LMAs in sizes suitable for smaller neonates and preterms, who could benefit from this additional interface option.

### **5.2 CPAP**

There are many neonatal airway interface devices on the market, but the issue of damage to nasal tissue remains a problem, particularly for CPAP therapy where a good fit is required in order to achieve clinically effective positive airway pressures. Tissue injury may be mitigated by the use of appropriately sized prongs, correct placement, and potentially alternating between different airway interfaces such as nasal masks.

There is potential for innovation through better design of the interface component that directly contacts the infant's skin, thoughtful material selection, and appropriate sizing for African and Asian nares. In addition, smaller sizes (especially for the orally placed LMA) are needed for very low-birthweight neonates as these do not currently exist.

Many of the CPAP airway interfaces are costly and are intended for single use. This, and lack of availability in LRS, means that healthcare workers must improvise and reuse airway interfaces, some of which may not be ideally suited to the application. Production of a lower-cost, single-use nasal airway interface or a reusable but easy-to-clean nasal airway interface has the potential to make CPAP therapy more widely available.

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