### Clinical question

In neonates receiving resuscitation (P) does the use of mouth-to-mouth, mouth-to-mask, mouth tube to mask (I) as compared to a self-inflating bag (C) give equivalent outcomes (stable spontaneous breathing) (O), when devices for delivering PPV are not available?

**Is this question addressing an intervention/therapy, prognosis or diagnosis?** Intervention/therapy

**State if this is a proposed new topic or revision of existing worksheet:** New topic

### Conflict of interest specific to this question

Do any of the authors listed above have conflict of interest disclosures relevant to this worksheet? No

### Search strategy (including electronic databases searched)

Searching in September, 2009 at: Embase, Medline, Cochrane, SciELO and LILACS databases (Portuguese and Spanish languages), Central registration of controlled trials, Google Scholar, with the following items:

- MESH terms: resuscitation AND newborn, infant AND low income settings (3 papers)
- MESH terms: resuscitation AND newborn, infant AND developing countries (100 papers)
- MESH terms: bag-and-mask AND newborn, infant AND developing countries (6 papers)
- MESH terms: mouth-to-mouth AND newborn, infant (18 papers)
- Words “mouth-to-mouth ventilation”, limited to all infant: birth to 23 months (11 papers)
- MESH terms: mouth-to-tube AND newborn, infant (4 papers)
- Words: “mouth-to-tube ventilation”, limited to all infant: birth to 23 months (2 papers)
- MESH terms: mouth-to-mask AND newborn, infant (3 papers)
- Words: “mouth-to-mask ventilation”, limited to all infant: birth to 23 months (3 papers)

Elegible publications in the reference lists of articles that met inclusion criteria.

### State inclusion and exclusion criteria

**Inclusion criteria:** Clinical trials with babies born at places of low-income resources that were ventilated with different devices in room air with outcomes related to birth asphyxia; and studies related to mouth-to-mouth, mouth-to-tube and mouth-to-mask ventilation in infants, or experimental models.

**Exclusion criteria:** animal studies; article reviews with comments and personal opinions regarding newborn ventilation in developing countries.

### Number of articles/sources meeting criteria for further review:

- Clinical trials related to the question – 2 articles (Massawe A at al, 1996; Bang et al, 2005).
- Studies related to infection risks –1 article (Roberts RB, Day RL, 1973)
- Investigations related to use and training – 4 articles and 1 internet publication (Terndrup TE, 1989; Milner et al, 1990; Milner et al, 1992; PATH, 2006; Coffey et al, 2007).

### Summary of evidence

<table>
<thead>
<tr>
<th>Evidence Supporting Clinical Question</th>
<th>Milner et al, 1990</th>
<th>Milner et al, 1992</th>
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<tr>
<td>Good</td>
<td>Milner et al, 1990 (mouth-tube-to-mask) - E</td>
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<td>Fair</td>
<td>Massawe et al, 1996 (mouth-to-mask) - E</td>
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<td>Bang at al, 2005 (mouth-tube-to-mask) - B</td>
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<td>PATH, 2006 (mouth-to-mask) and (mouth-tube-to-mask) - E</td>
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<td>Terndrup et al, 1989 (mouth-to-mask) - E</td>
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<td>Roberts, 1973 (mouth-to-tube) - E</td>
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### Level of evidence

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**A** = Return of spontaneous circulation  **C** = Survival to hospital discharge  
**B** = Survival of event  **D** = Intact neurological survival  
**E** = Other endpoint  
**Italics** = Animal studies
### Evidence Neutral to Clinical question

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#### Evidence Opposing Clinical Question

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### REVIEWER’S FINAL COMMENTS AND ASSESSMENT OF BENEFIT / RISK:

There is only one published study designed to compare improved spontaneous breathing at birth with different manual ventilation devices in places with low-income resources. Massawe et al (1996) (LOE2) studied 86 term and late preterm infants at birth that received mouth-to-mask ventilation and compared to 88 infants that received self-inflating bag and mask ventilation in India and Tanzania. This clinical trial shows that, at 35 insufflations/minute with room air, mouth-to-mask was similar to bag-and-mask ventilation to increase heart rate higher than 130 bpm at 5 minutes after birth, but the use of mouth-to-mask was very tiring and uncomfortable.

There is another study carried out in a rural region of India (Bang et al, 2005) (LOE3), but it was not specifically designed to compare the use of ventilation devices at birth. Authors describe 3 groups of unknown number of patients in 3 periods according to ventilation device use: mouth-to-mouth (1995-96), mouth-tube-to-mask (1996-1999), and self-inflating bag and mask (1999-2003). They concluded that mouth-tube-to-mask is as effective as bag-and-mask to decrease asphyxia related deaths compared to mouth-to-mouth ventilation when applied by trained traditional birth attendants at home deliveries, but the use of mouth-to-mask was very tiring and uncomfortable.

Related to use and training aspects, mouth-to-mask device was associated with adequate ventilation when compared to infant bag and mask device applied by emergency medical technicians-paramedics in infant mannequins (Terndrup et al, 1989) (LOE5). A mouth-to-tube device was considered effective by physicians at resuscitation (Roberts, 1973) (LOE 5). A mouth-tube-to-mask was used effectively in mannequins, with a minimum period of training, by people without previous resuscitation experience (Milner et al, 1990; Milner et al, 1992) (LOE5). In Indonesia, two self-inflating bags, one mouth-to-mask, and one mouth-tube-to-mask device were tested by 20 midwives and generated similar adequate ventilation pressures in mannequins. Tube-and-mask devices were cheaper and easier to clean than self inflating bag and mask (PATH, 2006) (LOE5). In a 2005 electronic survey with 22 health workers (88% from developing countries), there was a preference for the bag and mask due to its ease of use over the mouth-tube-to-mask device, which requires theuser to constantly bend forward and blow 30-40 times per minute (Coffey et al, 2007) (LOE5).

Regarding infectious risks, one article (Roberts, Day, 1973) (LOE5) describes bacterial growth in blood-agar plates after the experimenter exhaled through neonatal endotracheal tubes under conditions simulating resuscitation of neonates.

**Acknowledgements:** -
Citation List


LOE 3 – evidence supporting to clinical question (mouth-tube-to-mask)

LOE 3 – evidence opposing clinical question (mouth-to-mouth)

COMMENT:
Study design - Non-blind clinical trial using retrospective control
Where – 39 villages in Gadchiroli district in India
Patients – newborn infants at home delivery (89-95%)

Intervention 1 – 1995-1996 - mouth-to-mouth (MM) ventilation by trained traditional birth attendants (TBA)

Intervention 2 – 1996-1999 – mouth-to-tube-mask ventilation (silicon rubber tube with a safety valve) by trained TBA together with village health worker (with 5-10 years of schooling)

Comparison – 1999-2003 – self inflating bag and mask ventilation by trained TBA together with village health worker

Outcome – case fatality in severe asphyxia; asphyxia-specific mortality rate/1000 live births; fresh stillbirths/1000 births (=intrapartum fetal death or severe asphyxiated neonate that did not cry or breath). Trained village health workers observed newborns at 1 and 5 minutes after birth and an independent neonatologist reviewed the recorded neonatal data and assigned the most probable cause of death.

Ethics - Study approved by community consent in the form of signed resolution.

Outcome main results in the 3 periods:
Case fatality in severe asphyxia:
- Mouth-to-mouth vs Mouth-to-tube-mask - 38.5 vs 28%
- Mouth-tube-to-mask vs Bag and mask - 28.3 vs 17.2%
- Mouth-to-mouth vs Bag and mask - 38.5 vs 17.2% (p<0.05)

Asphyxia-specific mortality rate/1000 live births (AMRS):
- Mouth-to-mouth vs Mouth-tube-to-mask - 10.5 vs 3.5 (p<0.05) - reduction of AMRS of 41.8%
- Mouth-tube-to-mask vs Bag and mask - 3.5 vs 3.7
- Mouth-to-mouth vs Bag and mask - 10.5 vs 3.7 (p<0.05)

Fresh stillbirths/1000 births:
- Mouth-to-mouth vs Mouth-tube-to-mask - Not recorded
- Mouth-tube-to-mask vs Bag and mask - 18.4 vs 12.4
- Mouth-to-mouth vs Bag and mask - Not recorded

The study was not designed to compare different ventilation devices. The cohort comprises 5651 live births (1999 in the 1st period of mouth-to-mouth ventilation; 2512 in the 2nd period of tube-to-mask ventilation; 1140 live births in the 3rd period of bag-and-mask ventilation), but it is not known the number of infants that were ventilated and had stable spontaneous breathing.

This study shows mouth-to-mouth ventilation increases case fatality in severe asphyxia and asphyxia-specific mortality rate/1000 live births compared to use of bag and mask with room air.

This study shows similar case fatality in severe asphyxia and asphyxia-specific mortality rate/1000 live births with mouth-tube-to-mask or self inflating bag and mask ventilation with room air done by trained TBA and village health workers.

This article also mentions that village health workers prefer bag and mask because it was difficult to resuscitate up to 15 minutes using tube and mask at 30-40 times/minute, and they had to bend forward for 15 minutes, which is uncomfortable.


LOE 5 – evidence opposing to clinical question

COMMENT: Authors conducted an anonymous opinion electronic survey (2005) of neonatal experts about bag and mask and mouth-tube-to-mask use. Experts were identified through participant lists in global meetings on neonatal health. From 80 invited people, 22 (28%) answered, being 10 from subSaharan Africa, 4 from South and Southeast Asia, 2 from North America/Europe and 2 work globally. Eighteen respondents reported they have used a neonatal resuscitator in a developing country. Ease of use was the feature that mattered most for most of them. Bag and mask was preferred over a mouth-tube-to-mask device. Only 4 people had experience with mouth-tube-to-mask device and said that it requires the user to constantly bend forward and blow 30-40 times per minute, the infant is not visible during resuscitation, and it is difficult to tell if pressure being used is appropriate.

This study is included in the worksheet because it refers personal opinion about practical use regarding ventilation devices.

**LOE 2 – supporting to clinical question**

**COMMENT:**
Study design - Non-blind pseudo-randomized clinical trial (without description of randomization or power analysis)

Where - Two hospitals – A low-resource hospital in Dar es Salaam (Tanzania) with 17,000 deliveries/year with trained midwives and a Bombay hospital (India) with 4,500 deliveries/year with trained neonatologists;


**Patients** – term (mean 39 wks GA) and preterm (mean 35 wks) at birth;

**Intervention** - mouth to mask ventilation (mouth piece + connecting tube + one way valve + circular silicon rubber face mask)

**Comparison** - bag and mask ventilation with room air;

**Outcome** – Apgar scores at 1, 5 and 10 minutes; first gasp in 5 minutes; first cry in 5 minutes; time to achieve heart rate higher than 130 bpm; O2 Saturation > 75% within 5-6 minutes (one person was responsible for ventilating the baby and another other was responsible for recording physiological parameters with equipments).

Ethics - Study approved by ethics committee at each hospital.

Outcome at Dar es Salaam hospital - Midwives trained the two mode of ventilation for one month. Ventilation with mouth-to-mask with 30 breaths/minute was very tiring, therefore to avoid exhaustion during 10 minutes of assisted ventilation, it was reduced to 8-10 breaths/minute. In daytime, midwives ventilated 56 infants with mouth-to-mask (mean pressure 30 cmH2O and 8 insufflations/min) and 64 infants with B&M (mean pressure 30 and 10 insufflations/min). Outcomes were similar in term and preterm babies all born by vaginal delivery. Comparison mouth-to-mask (n=56) vs bag and mask (n=64):

- Apgar ≥ 4 at 1 minute - 29 vs 14% (p<0.05); at 5 minutes - 84 vs 77%; at 10 minutes - 98 vs 88% (p<0.05)
- First gasp in 5 minutes - 89 vs 81%; First cry in 5 minutes – 38 vs 41%; HR>130 bpm in 5 minutes - 40 vs 43%
- O2 Saturation > 75% within 5-6 minutes – not recorded

Outcome at Bombay hospital – neonatologists ventilated 30 infants with mouth-to-mask (mean pressure 30 and 33 insufflations/min) and 24 infants with BM (mean pressure 42 and 37 insufflations/min).

Comparison mouth-to-mask (n=30) vs B&M (n=24):

- Apgar ≥ 4 at 1 minute - 0 vs 8%; at 5 minutes - 77 vs 92%; at 10 minutes - 90 vs 100%
- First gasp in 5 minutes - 70 vs 96%; First cry in 5 minutes - 80 vs 70%; HR>130 bpm in 5 minutes - 78 vs 96%
- O2 Saturation > 75% within 5-6 minutes – 83 vs 80%

This study shows that outcome at 5 minutes after birth was similar either with **mouth-to-mask** or self inflating bag-and-mask ventilation at 35 insufflations/minute with room air. The use of mouth-to-mask is feasible, but is very tiring and uncomfortable.


**LOE 5 – evidence supporting to clinical question**

These articles do not have summary.

**COMMENT:** Authors describe a Laerdal facemask tube mouth resuscitator incorporating a disposable filter (mouth-tube-to-mask device). Fifteen nurses, doctors and midwives, and 15 lay public visitors were recruited to compare the use of this device and a conventional Laerdal infant bag and mask in a doll and in a ball in two centers (UK and Sweden). Participants received instructions for 2-5 minutes. Respiratory rates, maximum and mean inflation pressures and inspired times were similar between the 2 devices. Lay people consistently produced more satisfactory pressures than neonatal nurses, despite no previous experience, and were virtually identical to the midwife volunteers. This study is included in the worksheet because different ventilation methods are compared regarding applicability, even though in mannequins.

PATH. Reducing birth asphyxia through the Bidan di Desa Program in Cirebon, Indonesia: final report submitted by Program for Appropriate Technology in Health (PATH) to Save the Children US. Jakarta, Indonesia: PATH. March 15, 2006.

**LOE 5 – evidence supporting to clinical question (mouth-to-mask)**

**LOE 5 – evidence supporting to clinical question (mouth-tube-to-mask)**

**COMMENT:** This study was carried out in Indonesia to decrease mortality due to asphyxia. All local midwives and coordinators were trained in neonatal resuscitation with a national mouth-tube-to-mask device. Prior the training, 40 village midwives, using mannequins and a computer, compared this device with 2 types of bag and masks and to a mouth-to-mask device. The four devices
revealed adequate insufflation pressures. All BdsDs midwives were given neonatal resuscitation training and one mouth-tube-to-mask device to work with. On year after training it was observed that 85% of asphyxia cases were managed by village midwives and a significant decrease in neonatal mortality due to asphyxia. This study was included in the worksheet, because 4 ventilation devices were compared in a developing country before choosing the most appropriate to use in a live setting situation, mouth-tube-to-mask was used by all trained midwives at home births for at least a year, and mortality rate was followed before and after the use of this device.

LOE 5 – evidence supporting to clinical question

COMMENT: Author sent out questionnaires to all 164 members of Society for Obstetric and Perinatology, and 100 replied (59 anesthesiologists, 21 obstetricians, and 20 pediatricians). At that time, 23 mentioned that mouth-to-tube was their method of resuscitation, and 65 regarded the mouth-to-tube device as effective. Of 71 physicians who did not usually use mouth-to-tube resuscitation, 60 stated their reasons: alternative method (bag resuscitator) was better (55), low oxygen content of expired air (45), and danger of cross infection from operator (48). This study is included in the worksheet because relates preference practices.

LOE 5 – evidence opposing clinical question

COMMENT: Authors asked an experimenter to exhale through an endotracheal tube (ID 3 mm and 4 mm), as he would do in resuscitating a baby, in a 5-liter jar as a model for expanded infant’s lung with a blood-agar plate in it. The amount of bacterial growth was roughly proportional to the number of times operator blew. Then, authors describe a mouth-to-tube device with a flexible rubber diaphragm between operator’s mouth and the tube to decrease bacterial transmission to the infant through the tube. The main purpose of the study was to warn about the possibility of infant infection when ventilation is applied by mouth-tube ventilation without any valve. They do not mention about the risk of the health care provider acquired infection from the newborn infant. This study is included in the worksheet because relates risk for infection.

LOE 5 – evidence supporting to clinical question

COMMENT: This study shows that one mouth-to-mask device was as effective as infant bag and mask to ventilate mannequins, but caution must be taken with another model because of air leak between face mannequin and mask. This study is included in the worksheet because it compares different ventilation methods, even though, in mannequins.