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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Prehospital Airway Management

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Prehospital Airway Management,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before 30 days after the date of publication of this notice.

ADDRESSES:

E-mail submissions: epc@ahrq.hhs.gov

Print submissions:

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

Mail Stop 06E53A

Rockville, MD 20857

Shipping Address (FedEx, UPS, etc.):
Center for Evidence and Practice Improvement
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5600 Fishers Lane
Mail Stop 06E77D
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FOR FURTHER INFORMATION CONTACT:
Jenae Benns, Telephone: 301-427-1496 or Email: epc@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for Prehospital Airway Management. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Prehospital Airway Management*, including those that describe adverse events. The entire research protocol is available online at: https://effectivehealthcare.ahrq.gov/products/prehospital-airway-management/protocol

This is to notify the public that the EPC Program would find the following information on *Prehospital Airway Management* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number*.

- *For completed studies that do not have results on ClinicalTrials.gov*, a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.

- *A list of ongoing studies that your organization has sponsored for this indication*. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: https://www.effectivehealthcare.ahrq.gov/email-updates.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

Key Question 1

a. What are the comparative benefits and harms of bag valve mask versus supraglottic airway for patients requiring prehospital ventilatory support or airway protection?
b. Are the comparative benefits and harms modified by:
    i. Techniques or devices used?
    ii. Characteristics of emergency medical services personnel (including training, proficiency, experience, etc.)?
    iii. Patient characteristics?

Key Question 2

a. What are the comparative benefits and harms of bag valve mask versus endotracheal intubation for patients requiring prehospital ventilatory support or airway protection?
b. Are the comparative benefits and harms modified by:
    i. Techniques or devices used?
    ii. Characteristics of emergency medical services personnel (including training, proficiency, experience, etc.)?
    iii. Patient characteristics?

Key Question 3

a. What are the comparative benefits and harms of supraglottic airway versus endotracheal intubation for patients requiring prehospital ventilatory support or airway protection?
b. Are the comparative benefits and harms modified by:
    i. Techniques or devices used?

ii. Characteristics of emergency medical services personnel (including training, proficiency, experience, etc.)?
iii. Patient characteristics?

Key Question 4

What are the comparative benefits and harms of the following variations of any one of the three included airway interventions (bag valve mask, supraglottic airways, or endotracheal intubation) for patients requiring prehospital ventilatory support or airway protection:

i. Techniques or devices used?
ii. Characteristics of emergency medical services personnel (including training, proficiency, experience, etc.)?
iii. Patient characteristics?

PICOS (Populations, Interventions, Comparators, Outcomes, Settings, Study Design Settings)

PICOS	Inclusion Criteria	Exclusion Criteria
Populations	Patients requiring prehospital ventilatory support or airway protection who are treated in the prehospital setting by emergency medical services personnel (paramedic, advanced emergency medical technician, emergency medical technician, emergency medical responder, etc.)	• Patients treated with naloxone to reverse opioid-related respiratory failure • Patients cared for in other than the prehospital setting

Interventions	• Bag valve mask ventilation
	• Supraglottic airway insertion, including dual-lumen airways
	• Endotracheal intubation
	  ○ Via direct laryngoscopy with or without RSI or DSI
	  ○ Via video laryngoscopy with or without RSI or DSI
		• Nasotracheal intubation
		• Percutaneous devices
		• Surgical airway procedures
		• CPAP and BiPAP

Comparators	KQ1: bag valve mask vs. supraglottic airway KQ2: bag valve mask vs. endotracheal intubation KQ3: supraglottic airway vs. endotracheal intubation KQ4: different techniques for any one of the three included types of airways	• No airway management

PICOS	Inclusion Criteria	Exclusion Criteria

Outcomes	Patient Health Outcomes (highest priority)
	• Mortality/survival
	  ○ To arrival at hospital
	  ○ To hospital discharge
	  ○ Any period less than or equal to 30 days post-injury
	• Morbidity
	  ○ Glasgow Outcome Scale, Glasgow Outcome Scale Extended, Modified Rankin Scale, Cerebral Performance Category
	  ○ Pneumothorax
	  ○ Aspiration pneumonia
	• Length of Stay
	  ○ Hospital length of stay (days)
	  ○ ICU length of stay (days)
	  ○ ICU-free days
	Intermediate Outcomes (secondary priority)
	• Overall success rate
	• First pass success rate
	• Number of prehospital attempts to secure an airway
	• $EtCO_2$ values
	• Effective oxygenation
	• Effective ventilation
	• Definitive Airway Sans Hypoxia/Hypotension on First Attempt (DASH-1A)
	Adverse Events/Harms
	• Vomiting
	• Gastric content aspiration
	• Hypoxia (SpO_2<90%)
	• Hyperventilation ($EtCO_2$<35)
	• Hypoventilation (EtCO2>45)
	• Hypotension
	• Oral trauma, airway trauma
	• Barotrauma
	• Misplaced tube
	• Need for additional airway interventions
		Long-term outcomes (more than 30 days post-injury)

Setting	• Prehospital • ED only if needed to fill important gaps where there are no prehospital studies • International studies in English language	Airway studies conducted in cadaver labs, or simulated environments; operating rooms; or inpatient. ED studies if prehospital studies of the topic are available.
Study Design	• RCTs If RCTs do not provide sufficient evidence, the following designs will be included: • Prospective comparative studies • Retrospective comparative studies • Case control studies	• Systematic reviews (we will use reference lists to identify studies for possible inclusion) • Case series • Descriptive studies • Letters to the editor • Opinion papers • Studies published prior to 1990

BiPAP = bilevel positive airway pressure; CPAP = continuous positive airway pressure; DSI = delayed sequence intubation; ED = emergency department; ICU = intensive care unit; KQ = Key Question; RCT = randomized controlled trial; RSI = rapid sequence intubation

Dated: 26 February 2020.

Virginia L. Mackay-Smith,
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