# **Complete Summary**

#### **GUIDELINE TITLE**

Treatment: airway, ventilation, and oxygenation. In: Guidelines for the prehospital management of severe traumatic brain injury, second edition.

## **BIBLIOGRAPHIC SOURCE(S)**

Treatment: airway, ventilation, and oxygenation. In: Badjatia N, Carney N, Crocco TJ, Fallat ME, Hennes HM, Jagoda AS, Jernigan S, Lerner EB, Letarte PB, Moriarty T, Pons PT, Sasser S, Scalea TM, Schleien C, Wright DW. Guidelines for prehospital management of traumatic brain injury. 2nd ed. New York (NY): Brain Trauma Foundation; 2007. p. 42-60. [41 references]

#### **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: Brain Trauma Foundation. Guidelines for prehospital management of traumatic brain injury. New York (NY): Brain Trauma Foundation; 2000. 81 p.

## **COMPLETE SUMMARY CONTENT**

**SCOPE** 

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

## **SCOPE**

## **DISEASE/CONDITION(S)**

Traumatic brain injury (TBI)

## **GUIDELINE CATEGORY**

Evaluation Management Treatment

## **CLINICAL SPECIALTY**

Critical Care Emergency Medicine Neurological Surgery Neurology Pediatrics

#### **INTENDED USERS**

Emergency Medical Technicians/Paramedics Physicians

## **GUIDELINE OBJECTIVE(S)**

- To provide guidelines for the early and appropriate prehospital management of traumatic brain injury (TBI)
- To provide guidance on properly identifying and treating patients who need intubation

#### **TARGET POPULATION**

Adults and children with traumatic brain injury

### INTERVENTIONS AND PRACTICES CONSIDERED

Airway management and normal oxygenation:

- 1. Use of paralytics to assist intubation in patients who are able to maintain an oxygen saturation  $(SpO_2) > 90\%$  (not recommended)
- 2. Avoidance of hypoxemia and hyperventilation
- 3. Establishment of an airway
- 4. Monitoring of intubation (lung auscultation, end-tidal CO<sub>2</sub> [ETCO<sub>2</sub>] monitoring), blood pressure, and oxygenation

## **MAJOR OUTCOMES CONSIDERED**

- Morbidity and mortality from traumatic brain injury (TBI)
- Rate of misplaced intubations
- Length of stay in the intensive care unit (ICU)
- Length of hospitalization
- Days on a ventilator

#### **METHODOLOGY**

## METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

#### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

# **General Search Strategy**

Four participants were assigned to work on each topic – two for the adult section and two for the pediatric section. Participants finalized the scope of each topic and provided terms for the electronic literature search.

## **Inclusion Criteria**

- Human subjects
- Traumatic brain injury (TBI)
- English language
- >25 subjects
- Randomized controlled trials (RCTs), cohort studies, case-control studies, case series, databases, registries

#### **Exclusion Criteria**

- Sample contained >15% of pediatric patients, or > 15% of patients with pathologies other than TBI <u>AND</u> the data were not reported separately (see Appendix C of the original guideline document)
- Wrong independent variable (e.g., the intervention was not specific to the topic)
- Wrong dependent variable (e.g., outcomes were not mortality or morbidity, or did not associate with clinical outcomes)
- Statistics used in the analysis were not appropriate to the research design, variables, and/or sample size case studies, editorials, comments, letters

## **Literature Search and Retrieval**

Center staff worked with a doctoral-level research librarian to construct electronic search strategies for each topic from 1996 through April of 2005 to August 2005 (see Appendix B in the original guideline document). They used strategies with the highest likelihood of capturing most of the targeted literature, which resulted in the acquisition of a large proportion of non-relevant citations. A set of abstracts was sent to the participants for each topic. Blinded to each others' work, they read the abstracts and eliminated citations using the criteria specified above.

Center staff compared the participants' selections, identified discrepancies, and worked with authors to resolve them. A set of full-text publications was sent to each participant. They read the publications and determined the final library of studies that would be used as evidence. Results of the electronic searches were supplemented by recommendations of peers and by reading reference lists of included studies.

A second search was conducted from 2005 through July of 2006 to capture any relevant Class I or II literature that might have been published since the first literature search in 2005. Relevant publications were added to those from the original search, constituting the final library of studies that were used as evidence in this document. The yield of literature from each phase of the search is presented in Appendix D in the original guideline document.

# **Specific Strategy for This Topic**

For this update Medline was searched from 1996 through July 2006 using the search strategy for this question (see Appendix B in the original guideline document), and results were supplemented with literature recommended by peers or identified from reference lists. For adult studies, of 55 potentially relevant publications, 18 were added to the existing table and used as evidence for this question. For pediatric studies, of 62 potentially relevant publications, 4 were used as evidence for this question (see Evidence Tables in the original guideline document).

## **NUMBER OF SOURCE DOCUMENTS**

23 adult studies and 4 pediatric studies

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Class of Evidence	Study Design	Quality Criteria
I	Good quality randomized controlled	Adequate random assignment method.
	trial (RCT)	Allocation concealment.
		Groups similar at baseline.
		Outcome assessors blinded.
		Adequate sample size.
		Intention-to-treat analysis.

Class of Evidence	Study Design	Quality Criteria
		Follow-up rate >85%.
		Differential loss to follow-up.
		Maintenance of comparable groups.
II	Moderate quality RCT	Violation of one or more of the criteria for a good quality RCT. <sup>1</sup>
II	Good quality cohort	Blind or independent assessment in a prospective study, or use of reliable <sup>2</sup> data in a retrospective study.
		Comparison of two or more groups must be clearly distinguished.
		Non-biased selection.
		Follow-up rate >85%.
		Adequate sample size.
		Statistical analysis of potential confounders. <sup>3</sup>
II	Good quality case- control	Accurate ascertainment of cases.
		Nonbiased

Class of Evidence	Study Design	Quality Criteria
		selection of cases/controls with exclusion criteria applied equally to both.
		Adequate response rate.
		Appropriate attention to potential confounding variables.
III	Poor quality RCT	Major violations of the criteria for a good or moderate quality RCT. <sup>1</sup>
III	Moderate or poor quality cohort	Violation of one or more criteria for a good quality cohort. <sup>1</sup>
III	Moderate or poor quality case- control	Violation of one or more criteria for a good quality case-control. <sup>1</sup>
III	Case Series, Databases or Registries	Prospectively collected data that is purely observational, and retrospectively collected data.

<sup>1</sup>Assessor needs to make a judgment about whether one or more violations are sufficient to downgrade Class of study, based upon the topic, the seriousness of the violation(s), their potential impact on the results, and other aspects of the study. Two or three violations do not necessarily constitute a major flaw. The assessor needs to make a coherent argument why the violation(s) either do, or do not, warrant a downgrade.

<sup>&</sup>lt;sup>2</sup>Reliable data are concrete data such as mortality or re-operation.

<sup>&</sup>lt;sup>3</sup>Publication authors must provide a description

|--|

of robust baseline characteristics, and control for those that are unequally distributed between treatment groups.

#### METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

#### **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Remaining blinded to each other's work, participants read each publication and abstracted data using a predetermined format.

## **Quality of Body of Evidence**

Ultimately the individual studies were considered in aggregate, whether through meta-analyses or through qualitative assessment. Thus, the strength of recommendations were derived from the quality of the overall body of evidence used to address the topic.

The quality of the overall body of evidence for each recommendation was classified as *high*, *moderate*, or *low*. Factors that may decrease the quality include potential bias, differing findings across studies, the use of indirect evidence, or lack or precision. For example, if two or more Class I studies demonstrate contradictory findings for a particular topic, the overall quality most probably will be low because there is uncertainty about the effect. Similarly, Class I or II studies that provide indirect evidence may only constitute low quality evidence, overall.

#### **Indirect Evidence**

Well controlled studies conducted in the field are rare. One alternative is to apply evidence from studies conducted in other environments to field practice, or from other pathologies to traumatic brain injury (TBI). In this document, indirect evidence from inhospital populations or from physiological studies was used, after careful consideration of the quality of the study for its own population, and then of its usefulness as indirect evidence. The following sequential process of questions was used:

- 1. To what extent does the physiology of the field application approximate the physiology of the inhospital application?
- 2. What are the differences in patients, settings, treatments, and measurements between the field and inhospital settings?
- 3. To what extent would those differences influence the physiology of the intervention?
- 4. To what extent and in what direction would those differences influence the observed effect?
- 5. What is the quality of the publication?

6. Consider all of the above (1) to determine if the publication can be used as indirect evidence, and if so, (2) to determine the quality of the evidence.

In the original guideline document, indirect evidence used to support a recommendation is identified as such.

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Brain Trauma Foundation (BTF) and the BTF Center for Guidelines Management (Center) convened a virtual meeting of previous participants in the development of *Guidelines for Prehospital Management of Traumatic Brain Injury*, as well as with colleagues new to the project. They specified topics for inclusion in the current update, and agreed to include pediatric literature as a separate section for each topic. Further refinement of topics and scope was accomplished in a subsequent work meeting of participants with BTF and Center staff. The group agreed to maintain the distinction between *Assessment* topics and *Treatment* topics.

The participants drafted chapters and the entire team gathered for a 2-day work session to discuss the literature base, and to achieve consensus on classification of quality of evidence, and strength of recommendations.

After the work meeting, participants revised each topic based on the group's recommendations. Virtual meetings were convened, during which a subset of approximately five members of the team edited each topic online.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

**Strong** recommendations are derived from high quality evidence that provide precise estimates of the benefits or downsides of the topic being assessed.

With **weak** recommendations, (1) there is lack of confidence that the benefits outweigh the downsides, (2) the benefits and downsides may be equal, and/or (3) there is uncertainty about the degree of benefits and downsides.

## **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

## **METHOD OF GUIDELINE VALIDATION**

Internal Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Final versions were circulated to the Review Committee. Critiques from the Review Committee were addressed by participants and incorporated, or not, based upon their accuracy and consistency with the pre-specified systematic process.

## **RECOMMENDATIONS**

#### **MAJOR RECOMMENDATIONS**

Strength of recommendations (**strong** or **weak**) and quality of evidence (**Class I-III**) are defined at the end of the "Major Recommendations" field.

Strength of Recommendations: Weak.

Quality of Evidence: Low, primarily from Class III studies.

#### Adult

A. In ground transported patients in urban environments, the routine use of paralytics to assist endotracheal intubation in patients who are spontaneously breathing, and maintaining an oxygen saturation (SpO<sub>2</sub>) above 90% on supplemental oxygen, is not recommended.

#### **Adult and Pediatric**

- A. Hypoxemia ( $SpO_2 < 90\%$ ) should be avoided, and corrected immediately upon identification.
- B. An airway should be established, by the most appropriate means available, in patients who have severe traumatic brain injury (TBI) (Glasgow Coma Scale [GCS] <9), the inability to maintain an adequate airway, or hypoxemia not corrected by supplemental oxygen.
- C. Emergency Medical Service (EMS) systems implementing endotracheal intubation protocols including the use of rapid sequence intubation (RSI) protocols should monitor blood pressure, oxygenation, and when feasible, end-tidal carbon dioxide concentration in the expired air (ETCO<sub>2</sub>).
- D. When endotracheal intubation is used to establish an airway, confirmation of placement of the tube in the trachea should include lung auscultation and  $ETCO_2$  determination.
- E. Patients should be maintained with normal breathing rates (ETCO $_2$  35 to 40 mmHg), and hyperventilation (ETCO $_2$  <35 mmHg) should be avoided unless the patient shows signs of cerebral herniation (American Heart Association, 2005).

## **Definitions:**

#### **Quality of Evidence**

Class of Evidence	Study Design	Quality Criteria
I	Good	Adequate random

Class of Evidence	Study Design	Quality Criteria
	quality randomized controlled	assignment method.
	trial (RCT)	Allocation concealment.
		Groups similar at baseline.
		Outcome assessors blinded.
		Adequate sample size.
		Intention-to-treat analysis.
		Follow-up rate >85%.
		Differential loss to follow-up.
		Maintenance of comparable groups.
II	Moderate quality RCT	Violation of one or more of the criteria for a good quality RCT. <sup>1</sup>
II	Good quality cohort	Blind or independent assessment in a prospective study, or use of reliable <sup>2</sup> data in a retrospective study.
		Comparison of two or more groups must be clearly distinguished.

Class of Evidence	Study Design	Quality Criteria
		Non-biased selection.
		Follow-up rate >85%.
		Adequate sample size.
		Statistical analysis of potential confounders. <sup>3</sup>
II	Good quality case- control	Accurate ascertainment of cases.
	Control	Nonbiased selection of cases/controls with exclusion criteria applied equally to both.  Adequate response rate.  Appropriate attention to potential
		confounding variables.
III	Poor quality RCT	Major violations of the criteria for a good or moderate quality RCT. <sup>1</sup>
III	Moderate or poor quality cohort	Violation of one or more criteria for a good quality cohort. <sup>1</sup>
III	Moderate or poor quality case- control	Violation of one or more criteria for a good quality case-control. <sup>1</sup>
III	Case	Prospectively

Class of Evidence	Study Design	Quality Criteria
	Series, Databases or Registries	collected data that is purely observational, and retrospectively collected data.

<sup>1</sup>Assessor needs to make a judgment about whether one or more violations are sufficient to downgrade Class of study, based upon the topic, the seriousness of the violation(s), their potential impact on the results, and other aspects of the study. Two or three violations do not necessarily constitute a major flaw. The assessor needs to make a coherent argument why the violation(s) either do, or do not, warrant a downgrade.

<sup>2</sup>Reliable data are concrete data such as mortality or re-operation.

<sup>3</sup>Publication authors must provide a description of robust baseline characteristics, and control for those that are unequally distributed between treatment groups.

## **Strength of Recommendation**

**Strong** recommendations are derived from high quality evidence that provide precise estimates of the benefits or downsides of the topic being assessed.

With **weak** recommendations, (1) there is lack of confidence that the benefits outweigh the downsides, (2) the benefits and downsides may be equal, and/or (3) there is uncertainty about the degree of benefits and downsides.

## CLINICAL ALGORITHM(S)

None provided

# **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

#### REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

## TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

## **POTENTIAL BENEFITS**

Reduction in morbidity or mortality from severe traumatic brain injury (TBI) with prehospital airway, ventilation, and oxygenation management

#### **POTENTIAL HARMS**

Not stated

## **QUALIFYING STATEMENTS**

## **QUALIFYING STATEMENTS**

The information contained in these Guidelines, which reflects the current state of knowledge at the time of completion of the literature search (July 2006), is intended to provide accurate and authoritative information about the subject matter covered. Because there will be future developments in scientific information and technology, it is anticipated that there will be periodic review and updating of these Guidelines. These Guidelines are distributed with the understanding that the Brain Trauma Foundation, the National Highway Traffic Safety Administration, and the other organizations that have collaborated in the development of these Guidelines are not engaged in rendering professional medical services. If medical advice or assistance is required, the services of a competent physician should be sought. The recommendations contained in these Guidelines may not be appropriate for use in all circumstances. The decision to adopt a particular recommendation contained in these Guidelines must be based on the judgment of medical personnel, who take into consideration the facts and circumstances in each case, and on the available resources.

# IMPLEMENTATION OF THE GUIDELINE

## **DESCRIPTION OF IMPLEMENTATION STRATEGY**

An implementation strategy was not provided.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

#### **IOM CARE NEED**

Getting Better

# **IOM DOMAIN**

Effectiveness Safety

## **IDENTIFYING INFORMATION AND AVAILABILITY**

# **BIBLIOGRAPHIC SOURCE(S)**

Treatment: airway, ventilation, and oxygenation. In: Badjatia N, Carney N, Crocco TJ, Fallat ME, Hennes HM, Jagoda AS, Jernigan S, Lerner EB, Letarte PB, Moriarty T, Pons PT, Sasser S, Scalea TM, Schleien C, Wright DW. Guidelines for prehospital management of traumatic brain injury. 2nd ed. New York (NY): Brain Trauma Foundation; 2007. p. 42-60. [41 references]

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

## **DATE RELEASED**

2000 (revised 2007)

# **GUIDELINE DEVELOPER(S)**

Brain Trauma Foundation - Disease Specific Society
National Highway Traffic Safety Administration - Federal Government Agency
[U.S.]

# **SOURCE(S) OF FUNDING**

Brain Trauma Foundation

National Highway Traffic Safety Administration

#### **GUIDELINE COMMITTEE**

Not stated

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## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: Brain Trauma Foundation. Guidelines for prehospital management of traumatic brain injury. New York (NY): Brain Trauma Foundation; 2000. 81 p.

#### **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) from the <u>Brain</u> Trauma Foundation Web site.

Print copies: Available from the Brain Trauma Foundation, 708 Third Avenue, New York, NY 10017

#### **AVAILABILITY OF COMPANION DOCUMENTS**

None available

#### **PATIENT RESOURCES**

None available

# **NGC STATUS**

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