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Filing date: **10/19/2010**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91191601
Party	Defendant Anibal de Oliveira Fortuna
Correspondence Address	ANIBAL DE OLIVEIRA FORTUNA AV ALM COCHRANE, 83 APTO 161 SANTOS SP, 11040-001 BRAZIL anibal.fortuna@uol.com.br
Submission	Motion to Compel Discovery
Filer's Name	Anibal de Oliveira Fortuna
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Date	10/19/2010
Attachments	Applicant Discovery procedures current status1.pdf (20 pages)(181286 bytes)

Since September 29, 2009 this Applicant was submitted to 78 questions made by the Opposer's lawyers team and have thoughtfully answered to all of them at the best of his possibilities (Exhibit "A"). Those questions were divided between:

Applicant's Answer to Notice of Opposition (20);

Opposer's Request for Admissions:

first (28)

second (7)

third (7);

Opposer's Request for Interrogatories (12)

Opposer's Request for Production of Documents (4)

On the mean time, the Applicant has placed his ***First and only request for Admissions to the Opposer*** on August 31st, 2010, which the Opposer's layers have simply refused to accept and answer, allegedly an untimely delivery.

Applicant admits that he was somehow confused with the extensive Opposer's questionnaire, the US date notation and the followed successive changes in the date table, what leaded him to mail his answers to the Opposer's Third Request for Admissions on September 13, 2010, instead of September 10, 2010 (please notice that this September 10 was on a Friday and the next working day was actually, Monday, September 13, 2010), and to also forward its ***First and only request for Admissions to the Opposer***, 20 days after the previous closing date for the Discovery procedure.

On September 30, 2010 this Applicant has respectfully requested to this Board a 20 days' only TIME EXTENSION on the proposed DISCOVERY closing date, explaining the reasons for this unwilling initial delay, in order to provide the Opposer time to legally accept and ANSWER TO THE FIRST AND ONLY Applicant's request for Admissions to Opposer, an important evidence and substrate for the Applicant's defense.

Based on this motion, on October 5, 2010 the Board has re-arranged the time schedule for this process to the following dates:

Opposer's response to the motion is due: 10/17/2010.
Plaintiff's pretrial disclosures: 10/31/2010.
Plaintiff's 30-day Trial Period Ends 12/15/2010.
Defendant's Pretrial Disclosures 12/30/2010.
Defendant's 30-day Trial Period Ends 2/13/2011.
Plaintiff's Rebuttal Disclosures 2/28/2011.
Plaintiff's 15-day Rebuttal Period.
Ends 3/30/2011.

On October 15, 2010 the Opposer's lawyers have formally denied the Applicant's request for a 20 days extend on the proposed DISCOVERY closing date and have simply ignored important and undeniable evidences of this Applicant's good faith on his proposed mark registration.

In the interest of the truth and fair rights, this Applicant would like to respectfully request to this Board, to acknowledge the following evidence regarding a previous public use of the LMA acronym in question, employed generically as a reference to *laryngeal mask airways* devices, as part of the Applicant's defense to be further considered when necessary on this Board trial.

Evidence:

The American Society of Anesthesia (ASA), an US non-profit, educational, research and scientific association of national physicians founded in 1905, organized to raise and maintain the standards of the medical practice of anesthesiology and improve the care of the patients in its 2003 publication (Exhibit "B"), titled "*Practice Guidelines for Management of the Difficult Airway*", clearly says in its

“Recommendations”, fourth paragraph, page 1272, “*laryngeal mask airway (LMA)*” to generically refer to laryngeal masks supraglottal airway devices, as reproduced next:

Recommendations.

..... 4. *Actively pursue opportunities to deliver supplemental oxygen throughout the process of difficult airway management. Opportunities for supplemental oxygen administration include (but are not limited to) oxygen delivery by nasal cannulae, face mask, laryngeal mask airway (LMA), insufflation, or jet ventilation during intubation attempts; and oxygen delivery by face mask, blow-by, or nasal cannulae after extubation of the trachea.*

The American Society of Anesthesia (ASA) does not advocates the specific use of any particular brand or trademark of products in its public recommendations or guidelines, particularly on “Airway Management”, other than in certain occasions, when found didactically appropriate, to show a specific brand device as an example to illustrate possible options in that category.

Following its ethical and serious tradition, the American Society of Anesthesia (ASA) on this specific published “Recommendations”, by openly using the acronym “LMA” as a short for “laryngeal mask airway”, is certainly not specifically recommending the exclusive use of the Opposer’s brand (LMA trademark) of laryngeal masks, but instead, generically refereeing this to a class of products used on patient airway managements, which are served by several manufacturers, including the models made by the Opposer.

Respectfully submitted,

/aofortuna/

Anibal de Oliveira Fortuna
Applicant

Date: October 19, 2010

CERTIFICATE OF SERVICE

I hereby certify that a true and complete copy of the foregoing DISCOVERY PROCEDURES: ACTUAL STATUS on Applicant's procedures was served upon Opposer's by depositing a copy of the same on October 19th, 2010 at the Brazilian Postal Office, via First Class Certified Mail, postage prepaid, addressed to Counsel for Opposer at the following address:

Kelly M. Bargmann
Foley & Lardner LLP
90 Park Avenue
New York, NY 10016-1314
USA

/aofortuna/

Anibal de Oliveira Fortuna
Applicant

October 19, 2010

Sign electronically and sent to the Opposer legal representatives at the same time, via electronic mail to the following addresses: "bedwards@foley.com; jgriffith@foley.com; eschmalz@foley.com";

EXHIBIT "A"

1) Applicant's Answer to Notice of Opposition

CERTIFICATE OF SERVICE

I hereby certify that a true and complete copy of the foregoing Applicant's Answer to Notice of Opposition with Affirmative Defenses was served upon Opposer's by depositing a copy of the same on September 29, 2009 at the Brazilian Postal Office, via First Class Certified Mail, postage prepaid, addressed to Counsel for Opposer at the following address:

Kelly M. Bargmann
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90 Park Avenue
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Anibal de Oliveira Fortuna
Applicant

2) Applicant's Answer to Opposer's First Request for Admissions

CERTIFICATE OF SERVICE

I hereby certify that a true and complete copy of the foregoing Applicant's Answer to OPPOSER'S, THE LARYNGEAL MASK COMPANY LTD., FIRST REQUEST FOR ADMISSIONS TO APPLICANT ANIBAL DE OLIVEIRA FORTUNA was deposited on March 10, 2010 within the Brazilian Postal Office, via First Class Certified Mail, postage prepaid, addressed to Counsel for Opposer at the following address:

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Applicant

Sign electronically and sent to the Opposer at the same time, via electronic mail to the following addresses: "bedwards@foley.com; jgriffith@foley.com; mmurphy@foley.com";

3) Applicant's Answer to Opposer's Second Request for Admissions

CERTIFICATE OF SERVICE

I hereby certify that a true and complete copy of the foregoing Applicant's Answer to OPPOSER'S, THE LARYNGEAL MASK COMPANY LTD., SECOND REQUEST FOR ADMISSIONS TO APPLICANT ANIBAL DE OLIVEIRA FORTUNA was deposited on October 7, 2010 within the Brazilian Postal Office, via First Class Certified Mail, postage prepaid, addressed to Counsel for Opposer at the following address:

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Anibal de Oliveira Fortuna
Applicant

Sign electronically and sent to the Opposer legal representatives at the same time, via electronic mail to the following addresses: "bedwards@foley.com; jgriffith@foley.com; eschmalz@foley.com";

4) Applicant's Answer to Opposer's Third Request for Admissions

CERTIFICATE OF SERVICE

I hereby certify that a true and complete copy of the foregoing Applicant's Answer to OPPOSER'S, THE LARYNGEAL MASK COMPANY LTD., FIRST THIRD REQUEST FOR ADMISSIONS TO APPLICANT ANIBAL DE OLIVEIRA FORTUNA was deposited on September 13, 2010 within the Brazilian Postal Office, via First Class Certified Mail, postage prepaid, addressed to Counsel for Opposer at the following address:

Kelly M. Bargmann
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90 Park Avenue
New York, NY 10016-1314
USA

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Anibal de Oliveira Fortuna
Applicant

Sign electronically and sent to the Opposer legal representatives at the same time, via electronic mail to the following addresses: "bedwards@foley.com; jgriffith@foley.com; eschmalz@foley.com";

5) Applicant's Answer to Opposer's First Interrogatories

CERTIFICATE OF SERVICE

I hereby certify that a true and complete copy of the foregoing Applicant's Answer to OPPOSER'S, THE LARYNGEAL MASK COMPANY LTD., FIRST INTERROGATORIES was deposited on March 10, 2010 within the Brazilian Postal Office, via First Class Certified Mail, postage prepaid, addressed to Counsel for Opposer at the following address:

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90 Park Avenue
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Anibal de Oliveira Fortuna
Applicant

Sign electronically and sent to the Opposer at the same time, via electronic mail to the following addresses: "bedwards@foley.com; jgriffith@foley.com; mmurphy@foley.com";

6) Applicant's Answer to Opposer's First Request for Production of Documents and Things

CERTIFICATE OF SERVICE

I hereby certify that a true and complete copy of the foregoing Applicant's Answer to OPPOSER'S, THE LARYNGEAL MASK COMPANY LTD., FIRST REQUEST FOR PRODUCTION OF DOCUMENTS AND THINGS was deposited on March 10, 2010 within the Brazilian Postal Office, via First Class Certified Mail, postage prepaid, addressed to Counsel for Opposer at the following address:

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Anibal de Oliveira Fortuna
Applicant

Sign electronically and sent to the Opposer at the same time, via electronic mail to the following addresses: "bedwards@foley.com; jgriffith@foley.com; mmurphy@foley.com";

7) Applicant's First and only request for Admissions to Opposer

CERTIFICATE OF SERVICE

I hereby certify that a true and complete copy of the foregoing Applicant's ~~Answer to Notice of Opposition with Affirmative Defenses~~ Applicant's First request for Admissions to Opposer was served upon Opposer's by depositing a copy of the same on August 31st, 2010 at the Brazilian Postal Office, via First Class Certified Mail, postage prepaid, addressed to Counsel for Opposer at the following address:

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/aofortuna/

Anibal de Oliveira Fortuna
Applicant

8) Applicant's Motion for an Extend Time Request to Opposer

CERTIFICATE OF SERVICE

I hereby certify that a true and complete copy of the foregoing Applicant's MOTION FOR AN EXTEND TIME REQUEST to provide the Opposer time to ANSWER TO THE FIRST AND ONLY Applicant's request for Admissions to Opposer was served upon Opposer's by depositing a copy of the same on September 30rd, 2010 at the USPTO and by e-mail on next working day to the Opposer (as initially agreed between the both parts); also a copy on October 4th via First Class Certified Mail at the Brazilian Postal Office, postage prepaid, addressed to Counsel for Opposer at the following address:

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Anibal de Oliveira Fortuna
Applicant

Opposer's e-mails to were this Motion was served:

JGriffith@foley.com
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KWeiner@foley.com
ESchmalz@foley.com

EXHIBIT "B"

ATTACHED EVIDENCE:

1) American Society of Anesthesiologists (ASA): Practice Guidelines for Management of the Difficult Airway; *An Updated Report by the American Society of Anesthesiologists Task Force on Management of the Difficult Airway;* *Anesthesiology*, V 98, No 5, May 2003; (2003;98(5):1269–77) - © 2003 American Society of Anesthesiologists, Inc. Lippincott Williams & Wilkins, Inc.

Practice Guidelines for Management of the Difficult Airway

An Updated Report by the American Society of Anesthesiologists Task Force on Management of the Difficult Airway

PRACTICE guidelines are systematically developed recommendations that assist the practitioner and patient in making decisions about health care. These recommendations may be adopted, modified, or rejected according to clinical needs and constraints.

Practice guidelines are not intended as standards or absolute requirements. The use of practice guidelines cannot guarantee any specific outcome. Practice guidelines are subject to revision as warranted by the evolution of medical knowledge, technology, and practice. They provide basic recommendations that are supported by analysis of the current literature and by a synthesis of expert opinion, open forum commentary, and clinical feasibility data.

This revision includes data published since the "Practice Guidelines for Management of the Difficult Airway" were adopted by the American Society of Anesthesiologists in 1992; it also includes data and recommendations for a wider range of management techniques than was previously addressed.

A. Definition

A standard definition of the difficult airway cannot be identified in the available literature. For these Guidelines, a *difficult airway* is defined as the clinical situation in which a conventionally trained anesthesiologist expe-

periences difficulty with face mask ventilation of the upper airway, difficulty with tracheal intubation, or both.

The difficult airway represents a complex interaction between patient factors, the clinical setting, and the skills of the practitioner. Analysis of this interaction requires precise collection and communication of data. The Task Force urges clinicians and investigators to use explicit descriptions of the difficult airway. Descriptions that can be categorized or expressed as numerical values are particularly desirable, as this type of information lends itself to aggregate analysis and cross-study comparisons. Suggested descriptions include (but are not limited to):

1. Difficult face mask ventilation: (a) It is not possible for the anesthesiologist to provide adequate face mask ventilation due to one or more of the following problems: inadequate mask seal, excessive gas leak, or excessive resistance to the ingress or egress of gas. (b) Signs of inadequate face mask ventilation include (but are not limited to) absent or inadequate chest movement, absent or inadequate breath sounds, auscultatory signs of severe obstruction, cyanosis, gastric air entry or dilatation, decreasing or inadequate oxygen saturation (SpO₂), absent or inadequate exhaled carbon dioxide, absent or inadequate spirometric measures of exhaled gas flow, and hemodynamic changes associated with hypoxemia or hypercarbia (e.g., hypertension, tachycardia, arrhythmia).
2. Difficult laryngoscopy: (a) It is not possible to visualize any portion of the vocal cords after multiple attempts at conventional laryngoscopy.
3. Difficult tracheal intubation: (a) Tracheal intubation requires multiple attempts, in the presence or absence of tracheal pathology.
4. Failed intubation: (a) Placement of the endotracheal tube fails after multiple intubation attempts.

B. Purpose of the Guidelines for Difficult Airway Management

The purpose of these Guidelines is to facilitate the management of the difficult airway and to reduce the likelihood of adverse outcomes. The principal adverse outcomes associated with the difficult airway include (but are not limited to) death, brain injury, cardiopulmonary arrest, unnecessary tracheostomy, airway trauma, and damage to teeth.

Additional material related to this article can be found on the ANESTHESIOLOGY Web site. Go to the following address, click on Enhancements Index, and then scroll down to find the appropriate article and link. <http://www.anesthesiology.org>

Developed by the American Society of Anesthesiologists Task Force on Difficult Airway Management: Robert A. Caplan, M.D. (Chair), Seattle, Washington; Jonathan L. Benumof, M.D., San Diego, California; Frederic A. Berry, M.D., Charlottesville, Virginia; Casey D. Blitt, M.D., Tucson, Arizona; Robert H. Bode, M.D., Boston, Massachusetts; Frederick W. Cheney, M.D., Seattle, Washington; Richard T. Connis, Ph.D., Woodinville, Washington; Orin F. Guidry, M.D., Jackson, Mississippi; David G. Nickinovich, Ph.D., Bellevue, Washington; and Andranik Ovassapian, M.D., Chicago, Illinois. Submitted for publication October 23, 2002. Accepted for publication October 23, 2002. Supported by the American Society of Anesthesiologists under the direction of James F. Arens, M.D., Chair, Committee on Practice Parameters. A list of the references used to develop these Guidelines is available by writing to the American Society of Anesthesiologists.

Address reprint requests to the American Society of Anesthesiologists: 520 North Northwest Highway, Park Ridge, Illinois 60068-2573. Individual Practice Guidelines may be obtained at no cost through the Journal Web site, www.anesthesiology.org.

C. Focus

The primary focus of these Guidelines is the management of the difficult airway encountered during administration of anesthesia and tracheal intubation. Some aspects of the Guidelines may be relevant in other clinical contexts. The Guidelines do not represent an exhaustive consideration of all manifestations of the difficult airway or all possible approaches to management.

D. Application

The Guidelines are intended for use by anesthesiologists and by individuals who deliver anesthetic care and airway management under the direct supervision of an anesthesiologist. The Guidelines apply to all types of anesthetic care and airway management delivered in anesthetizing locations and is intended for all patients of all ages.

E. Task Force Members and Consultants

The American Society of Anesthesiologists (ASA) appointed a Task Force of 10 members to (1) review the published evidence, (2) obtain the opinions of anesthesiologists selected by the Task Force as consultants, and (3) build consensus within the community of practitioners likely to be affected by the Guidelines. The Task Force included anesthesiologists in both private and academic practices from various geographic areas of the United States and consulting methodologists from the ASA Committee on Practice Parameters.

These Practice Guidelines update and revise the 1993 publication of the ASA "Guidelines for Management of the Difficult Airway."^{*} The Task Force revised and updated the Guidelines by means of a five-step process. First, original published research studies relevant to the revision and update were reviewed and analyzed. Second, the panel of expert consultants was asked to (1) participate in a survey related to the effectiveness and safety of various methods and interventions that might be used during management of the difficult airway, and (2) review and comment on draft reports. Third, the Task Force held an open forum at a major national anesthesia meeting to solicit input from attendees on a draft of the Guidelines. Fourth, the consultants were surveyed to assess their opinions on the feasibility and financial implications of implementing the Guidelines. Finally, all of the available information was used by the Task Force to finalize the Guidelines.

^{*} Practice guidelines for the difficult airway: A report by the American Society of Anesthesiologists Task Force on Management of the Difficult Airway. *ANESTHESIOLOGY* 1993; 78:597-602

F. Availability and Strength of Evidence

Evidence-based guidelines are developed by a rigorous analytic process (Appendix). To assist the reader, these Guidelines make use of several descriptive terms that are easier to understand than the technical terms and data that are used in the actual analyses. These descriptive terms are defined below.

The following terms describe the *strength* of scientific data obtained from the scientific literature.

Supportive: There is sufficient quantitative information from adequately designed studies to describe a statistically significant relationship ($P < 0.01$) between a clinical intervention and a clinical outcome, using meta-analysis.

Suggestive: There is enough information from case reports and descriptive studies to provide a directional assessment of the relationship between a clinical intervention and a clinical outcome. This type of qualitative information does not permit a statistical assessment of significance.

Equivocal: Qualitative data have not provided a clear direction for clinical outcomes related to a clinical intervention, and (1) there is insufficient quantitative information, or (2) aggregated comparative studies have found no quantitatively significant differences among groups or conditions.

The following terms describe the *lack* of available scientific evidence in the literature.

Inconclusive: Published studies are available, but they cannot be used to assess the relationship between a clinical intervention and a clinical outcome because the studies either do not meet predefined criteria for content, as defined in the "Focus" of these Guidelines, or do not provide a clear causal interpretation of findings because of research design or analytic concerns.

Insufficient: There are too few published studies to investigate a relationship between a clinical intervention and clinical outcome.

Silent: No studies that address a relationship of interest were found in the available published literature.

The following terms describe survey responses from the consultants for any specified issue.

Responses are assigned a numeric value of agree = +1, undecided = 0, or disagree = -1. The average weighted response represents the mean value for each survey item.

Agree: The average weighted response must be equal to or greater than +0.30 (on a scale of -1 to 1) to indicate agreement.

Equivocal: The average weighted response must be between -0.30 and +0.30 (on a scale of -1 to 1) to indicate an equivocal response.

Table 1. Components of the Preoperative Airway Physical Examination

Airway Examination Component	Nonreassuring Findings
1. Length of upper incisors	Relatively long
2. Relation of maxillary and mandibular incisors during normal jaw closure	Prominent "overbite" (maxillary incisors anterior to mandibular incisors)
3. Relation of maxillary and mandibular incisors during voluntary protrusion of cannot bring	Patient mandibular incisors anterior to (in mandible front of) maxillary incisors
4. Interincisor distance	Less than 3 cm
5. Visibility of uvula	Not visible when tongue is protruded with patient in sitting position (e.g., Mallampati class greater than II)
6. Shape of palate	Highly arched or very narrow
7. Compliance of mandibular space	Stiff, indurated, occupied by mass, or nonresilient
8. Thyromental distance	Less than three ordinary finger breadths
9. Length of neck	Short
10. Thickness of neck	Thick
11. Range of motion of head and neck	Patient cannot touch tip of chin to chest or cannot extend neck

This table displays some findings of the airway physical examination that may suggest the presence of a difficult intubation. The decision to examine some or all of the airway components shown in this table depends on the clinical context and judgment of the practitioner. The table is not intended as a mandatory or exhaustive list of the components of an airway examination. The order of presentation in this table follows the "line of sight" that occurs during conventional oral laryngoscopy.

Disagree: The average weighted response must be equal to or less than -0.30 (on a scale of -1 to 1) to indicate disagreement.

Guidelines

I. Evaluation of the Airway

1. History. There is insufficient published evidence to evaluate the effect of a bedside medical history on predicting the presence of a difficult airway. Similarly, there is insufficient evidence to evaluate the effect of reviewing prior medical records on predicting the presence of a difficult airway. There is suggestive evidence that some features of a patient's medical history or prior medical records may be related to the likelihood of encountering a difficult airway. This support is based on recognized associations between a difficult airway and a variety of congenital, acquired, or traumatic disease states. In addition, the Task Force believes that the description of a difficult airway on a previous anesthesia record or anesthesia document offers clinically suggestive evidence that difficulty may recur. The consultants and Task Force agree that a focused bedside medical history and a focused review of medical records may improve the detection of a difficult airway.

Recommendations. An airway history should be conducted, whenever feasible, prior to the initiation of anesthetic care and airway management in all patients. The intent of the airway history is to detect medical, surgical, and anesthetic factors that may indicate the presence of a difficult airway. Examination of previous anesthetic records, if available in a timely manner, may yield useful information about airway management.

II. Physical Examination

In patients with no gross upper airway pathology or anatomical anomaly, there is insufficient published evi-

dence to evaluate the effect of a physical examination on predicting the presence of a difficult airway. However, there are suggestive data that findings obtained from an airway physical examination may be related to the presence of a difficult airway. This support is based on recognized associations between the difficult airway and a variety of airway characteristics. The consultants and Task Force agree that an airway physical examination may improve the detection of a difficult airway.

Specific features of the airway physical examination have been incorporated into rating systems intended to predict the likelihood of a difficult airway. Existing rating systems have been shown to exhibit modest sensitivity and specificity. The specific effect of the airway physical examination on outcome has not been clearly defined in the literature.

There is insufficient published evidence to evaluate the predictive value of single features of the airway physical examination *versus* multiple features in predicting the presence of a difficult airway. The consultants and Task Force agree that prediction of a difficult airway may be improved by the assessment of multiple features. The Task Force does not regard any rating system as fail-safe.

Recommendations. An airway physical examination should be conducted, whenever feasible, prior to the initiation of anesthetic care and airway management in all patients. The intent of this examination is to detect physical characteristics that may indicate the presence of a difficult airway. Multiple airway features should be assessed (table 1).

III. Additional Evaluation

The airway history or physical examination may provide indications for additional diagnostic testing in some patients. The literature suggests that certain diagnostic tests may identify features associated with a difficult

airway. The literature does not provide a basis for using specific diagnostic tests as routine screening tools in the evaluation of the difficult airway.

Recommendations. Additional evaluation may be indicated in some patients to characterize the likelihood or nature of the anticipated airway difficulty. The findings of the airway history and physical examination may be useful in guiding the selection of specific diagnostic tests and consultation.

IV. Basic Preparation for Difficult Airway Management

The literature is silent regarding the benefits of informing the patient of a known or suspected difficult airway, the availability of equipment for difficult airway management, or the availability of an individual to provide assistance when a difficult airway is encountered. However, there is strong agreement among consultants that preparatory efforts enhance success and minimize risk.

The literature suggests that either traditional preoxygenation (3 or more minutes of tidal volume ventilation) or fast-track preoxygenation (*i.e.*, four maximal breaths in 30 s) is effective in delaying arterial desaturation during subsequent apnea. The literature supports the greater efficacy of traditional preoxygenation when compared to fast-track preoxygenation in delaying arterial desaturation during apnea.

The literature supports the efficacy of supplemental oxygen in reducing hypoxemia after extubation of the trachea.

Recommendations. At least one portable storage unit that contains specialized equipment for difficult airway management should be readily available. Specialized equipment suggested by the Task Force is listed in table 2.

If a difficult airway is known or suspected, the anesthesiologist should

1. Inform the patient (or responsible person) of the special risks and procedures pertaining to management of the difficult airway.
2. Ascertain that there is at least one additional individual who is immediately available to serve as an assistant in difficult airway management.
3. Administer face mask preoxygenation before initiating management of the difficult airway. The uncooperative or pediatric patient may impede opportunities for preoxygenation.
4. Actively pursue opportunities to deliver supplemental oxygen throughout the process of difficult airway management. Opportunities for supplemental oxygen administration include (but are not limited to) oxygen delivery by nasal cannulae, face mask, laryngeal mask airway (LMA), insufflation, or jet ventilation during intubation attempts; and oxygen delivery by face mask, blow-by, or nasal cannulae after extubation of the trachea.

Table 2. Suggested Contents of the Portable Storage Unit for Difficult Airway Management

1. Rigid laryngoscope blades of alternate design and size from those routinely used; this may include a rigid fiberoptic laryngoscope
2. Tracheal tubes of assorted sizes
3. Tracheal tube guides. Examples include (but are not limited to) semirigid stylets, ventilating tube changer, light wands, and forceps designed to manipulate the distal portion of the tracheal tube
4. Laryngeal mask airways of assorted sizes; this may include the intubating laryngeal mask airway and the *LMA-Proseal*TM (LMA North America, Inc., San Diego, CA)
5. Flexible fiberoptic intubation equipment
6. Retrograde intubation equipment
7. At least one device suitable for emergency noninvasive airway ventilation. Examples include (but are not limited to) an esophageal tracheal Combitube (Kendall-Sheridan Catheter Corp., Argyle, NY), a hollow jet ventilation stylet, and a transtracheal jet ventilator
8. Equipment suitable for emergency invasive airway access (*e.g.*, cricothyrotomy)
9. An exhaled CO₂ detector

The items listed in this table represent suggestions. The contents of the portable storage unit should be customized to meet the specific needs, preferences, and skills of the practitioner and healthcare facility.

V. Strategy for Intubation of the Difficult Airway

The literature suggests that the use of specific strategies facilitates the intubation of the difficult airway. Although the degree of benefit for any specific strategy cannot be determined from the literature, there is strong agreement among consultants that a *preplanned strategy* may lead to improved outcome.

Preplanned strategies can be linked together to form airway management *algorithms*. The Task Force considers the technical and physiologic complexity of life-threatening airway events to be sufficiently similar to life-threatening cardiac events to encourage the use of algorithms in difficult airway management.

Recommendations. The anesthesiologist should have a preformulated strategy for intubation of the difficult airway. The algorithm shown in figure 1 is a strategy recommended by the Task Force. This strategy will depend, in part, on the anticipated surgery, the condition of the patient, and the skills and preferences of the anesthesiologist.

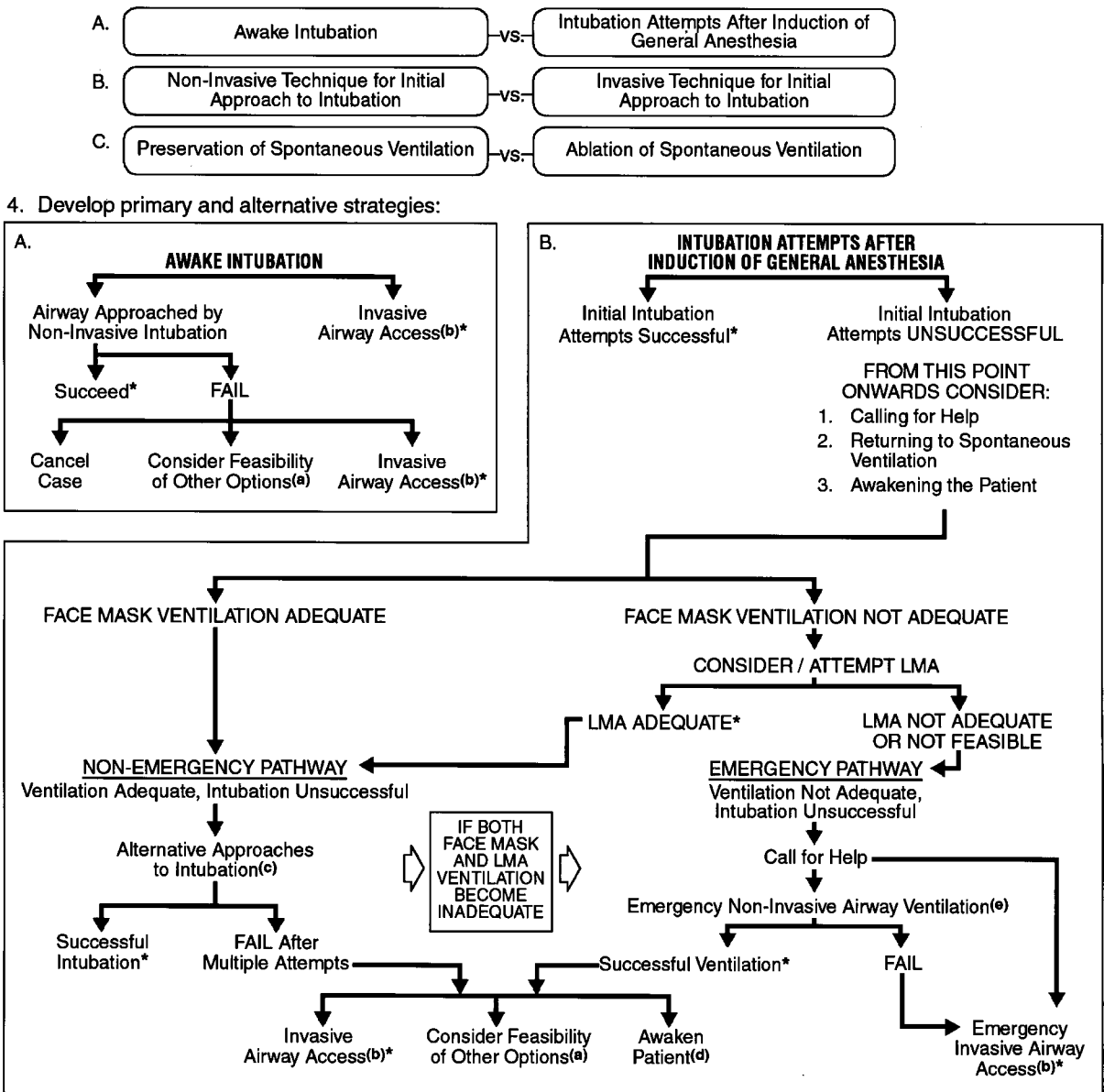
The strategy for intubation of the difficult airway should include

1. An assessment of the likelihood and anticipated clinical impact of four basic problems that may occur alone or in combination:
 - a. difficult ventilation
 - b. difficult intubation
 - c. difficulty with patient cooperation or consent
 - d. difficult tracheostomy
2. A consideration of the relative clinical merits and feasibility of three basic management choices:



DIFFICULT AIRWAY ALGORITHM

1. Assess the likelihood and clinical impact of basic management problems:
 - A. Difficult Ventilation
 - B. Difficult Intubation
 - C. Difficulty with Patient Cooperation or Consent
 - D. Difficult Tracheostomy
2. Actively pursue opportunities to deliver supplemental oxygen throughout the process of difficult airway management
3. Consider the relative merits and feasibility of basic management choices:
 - A. Awake Intubation vs. Intubation Attempts After Induction of General Anesthesia
 - B. Non-Invasive Technique for Initial Approach to Intubation vs. Invasive Technique for Initial Approach to Intubation
 - C. Preservation of Spontaneous Ventilation vs. Ablation of Spontaneous Ventilation



* Confirm ventilation, tracheal intubation, or LMA placement with exhaled CO₂

- a. Other options include (but are not limited to): surgery utilizing face mask or LMA anesthesia, local anesthesia infiltration or regional nerve blockade. Pursuit of these options usually implies that mask ventilation will not be problematic. Therefore, these options may be of limited value if this step in the algorithm has been reached via the Emergency Pathway.
- b. Invasive airway access includes surgical or percutaneous tracheostomy or cricothyrotomy.
- c. Alternative non-invasive approaches to difficult intubation include (but are not limited to): use of different laryngoscope blades, LMA as an intubation conduit (with or without fiberoptic guidance), fiberoptic intubation, intubating stylet or tube changer, light wand, retrograde intubation, and blind oral or nasal intubation.
- d. Consider re-preparation of the patient for awake intubation or canceling surgery.
- e. Options for emergency non-invasive airway ventilation include (but are not limited to): rigid bronchoscope, esophageal-tracheal combitube ventilation, or transtracheal jet ventilation.

Fig. 1. Anesthesiology, V 98, No 5, May 2003

Table 3. Techniques for Difficult Airway Management

Techniques for Difficult Intubation	Techniques for Difficult Ventilation
Alternative laryngoscope blades	Esophageal tracheal Combitube
Awake intubation	Intratracheal jet stylet
Blind intubation (oral or nasal)	Laryngeal mask airway
Fiberoptic intubation	Oral and nasopharyngeal airways
Intubating stylet or tube changer	Rigid ventilating bronchoscope
Laryngeal mask airway as an intubating conduit	Invasive airway access
Light wand	Transtacheal jet ventilation
Retrograde intubation	Two-person mask ventilation
Invasive airway access	

This table displays commonly cited techniques. It is not a comprehensive list. The order of presentation is alphabetical and does not imply preference for a given technique or sequence of use. Combinations of techniques may be employed. The techniques chosen by the practitioner in a particular case will depend upon specific needs, preferences, skills, and clinical constraints.

- a. awake intubation *versus* intubation after induction of general anesthesia
 - b. use of noninvasive techniques for the initial approach to intubation *versus* the use of invasive techniques (*i.e.*, surgical or percutaneous tracheostomy or cricothyrotomy)
 - c. preservation of spontaneous ventilation during intubation attempts *versus* abolition of spontaneous ventilation during intubation attempts
3. The identification of a primary or preferred approach to:
 - a. awake intubation
 - b. the patient who can be adequately ventilated but is difficult to intubate
 - c. the life-threatening situation in which the patient cannot be ventilated or intubated
 4. The identification of alternative approaches that can be employed if the primary approach fails or is not feasible:
 - a. Table 3 displays options for difficult airway management.
 - b. The uncooperative or pediatric patient may restrict the options for difficult airway management, particularly options that involve awake intubation. Airway management in the uncooperative or pediatric patient may require an approach (*e.g.*, intubation attempts after induction of general anesthesia) that might not be regarded as a primary approach in a cooperative patient.
 - c. The conduct of surgery using local anesthetic infiltration or regional nerve blockade may provide an alternative to the direct management of the difficult airway, but this approach does not represent a definitive solution to the presence of a difficult airway, nor does it obviate the need for a

preformulated strategy for intubation of the difficult airway.

5. The use of exhaled carbon dioxide to confirm tracheal intubation.

VI. Strategy for Extubation of the Difficult Airway

The literature does not provide a sufficient basis for evaluating the benefits of an extubation strategy for the difficult airway. The Task Force regards the concept of an extubation strategy as a logical extension of the intubation strategy. Consultant opinion strongly supports the use of an extubation strategy.

Recommendations. The anesthesiologist should have a preformulated strategy for extubation of the difficult airway. This strategy will depend, in part, on the surgery, the condition of the patient, and the skills and preferences of the anesthesiologist.

The preformulated extubation strategy should include

1. A consideration of the relative merits of awake extubation versus extubation before the return of consciousness.
2. An evaluation for general clinical factors that may produce an adverse impact on ventilation after the patient has been extubated.
3. The formulation of an airway management plan that can be implemented if the patient is not able to maintain adequate ventilation after extubation.
4. A consideration of the short-term use of a device that can serve as a guide for expedited reintubation. This type of device is usually inserted through the lumen of the tracheal tube and into the trachea before the tracheal tube is removed. The device may be rigid to facilitate intubation and/or hollow to facilitate ventilation.

VII. Follow-up Care

Although the literature is insufficient to evaluate the benefits of follow-up care, this activity is strongly supported by consultant opinion. The Task Force has identified several fundamental concepts that merit consideration.

Recommendations. The anesthesiologist should document the presence and nature of the airway difficulty in the medical record. The intent of this documentation is to guide and facilitate the delivery of future care. Aspects of documentation that may prove helpful include (but are not limited to)

1. A description of the airway difficulties that were encountered. The description should distinguish between difficulties encountered in face mask or LMA ventilation and difficulties encountered in tracheal intubation.
2. A description of the various airway management techniques that were employed. The description should indicate the extent to which each of the techniques

served a beneficial or detrimental role in management of the difficult airway.

The anesthesiologist should inform the patient (or responsible person) of the airway difficulty that was encountered. The intent of this communication is to provide the patient (or responsible person) with a role in guiding and facilitating the delivery of future care. The information conveyed may include (but is not limited to) the presence of a difficult airway, the apparent reasons for difficulty, how the intubation was accomplished, and the implications for future care. Notification systems, such as a written report or letter to the patient, a written report in the medical chart, communication with the patient's surgeon or primary caregiver, a notification bracelet or equivalent identification device, or chart flags, may be considered.

The anesthesiologist should evaluate and follow up with the patient for potential complications of difficult airway management. These complications include (but are not limited to) edema, bleeding, tracheal and esophageal perforation, pneumothorax, and aspiration. The patient should be advised of the potential clinical signs and symptoms associated with life-threatening complications of difficult airway management. These signs and symptoms include (but are not limited to) sore throat, pain or swelling of the face and neck, chest pain, subcutaneous emphysema, and difficulty swallowing.

Appendix: Methods and Analyses

The scientific assessment of these Guidelines was based on the following statements or evidence linkages. These linkages represent directional statements about relationships between clinical care and clinical outcome in difficult airway management.

1. Evaluation of the airway: (a) A directed history detects a difficult airway and reduces airway-related adverse outcomes. (b) A directed airway physical examination detects a difficult airway and reduces airway-related adverse outcomes. (c) Diagnostic tests (e.g., radiography) detect a difficult airway and reduce airway-related adverse outcomes.
2. Basic preparation for difficult airway management: (a) Informing the patient with a known or suspected difficult airway reduces airway-related adverse outcomes. (b) Availability of equipment for management of a difficult airway (i.e., a portable storage unit) reduces airway-related adverse outcomes. (c) Availability of an assigned individual to provide assistance when a difficult airway is encountered reduces airway-related adverse outcomes. (d) Preanesthetic preoxygenation by face mask before induction of anesthesia delays arterial desaturation and prevents hypoxemia during subsequent apnea.
3. Strategies for intubation and ventilation:
 - a. Awake intubation improves intubation success and reduces airway-related adverse outcomes.
 - b. Adequate face mask ventilation after induction:
 - (1) Rigid laryngoscopic blades of alternative design or size improve intubation success and reduce airway-related adverse outcomes.
 - (2) Fiberoptic guided intubation improves intubation success and reduces airway-related adverse outcomes.
 - (3) An intubating stylet, tube changer, or gum elastic bougie improves intubation success and reduces airway-related adverse outcomes.
 - (4) A lighted stylet or light wand improves intubation success and reduces airway-related adverse outcomes.
 - (5) Retrograde intubation improves intubation success and reduces airway-related adverse outcomes.
- (c) The laryngeal mask airway:
 - (1) The laryngeal mask airway improves ventilation and reduces airway-related adverse outcomes.
 - (2) The laryngeal mask airway *versus* face mask improves ventilation and reduces airway-related adverse outcomes.
 - (3) The laryngeal mask airway *versus* tracheal intubation results in equivalent ventilation and reduces perioperative airway-related outcomes.
 - (4) The laryngeal mask airway *versus* oropharyngeal airway results in equivalent ventilation and reduces perioperative airway-related outcomes.
 - (5) The laryngeal mask airway as an intubation conduit reduces airway-related adverse outcomes.
- (d) Inadequate face mask ventilation after induction—cannot intubate:
 - (1) The laryngeal mask airway for emergency ventilation reduces airway-related adverse outcomes.
 - (2) A rigid bronchoscope for difficult airway management reduces airway-related adverse outcomes.
 - (3) The esophageal tracheal Combitube (Kendall-Sheridan Catheter Corp., Argyle, NY) for difficult airway management reduces airway-related adverse outcomes.
 - (4) Transtracheal jet ventilation reduces airway-related adverse outcomes.
4. Confirmatory tests of tracheal intubation: (a) Capnography or end-tidal carbon dioxide detection verifies tracheal intubation and leads to fewer adverse outcomes. (b) Other confirmatory tests (i.e., esophageal detectors or self-inflating bulbs) verify tracheal intubation and lead to fewer adverse outcomes. (c) Fiberoptic confirmation of tracheal intubation
5. Awake extubation: (a) Awake extubation reduces airway-related adverse outcomes.
6. Supplemental oxygen: (a) Supplemental oxygen delivery before induction by face mask or insufflation reduces airway-related adverse outcomes. (b) Supplemental oxygen delivery after extubation by face mask, blow-by, or nasal cannulae of the trachea reduces airway-related adverse outcomes.
7. Follow-up care: (a) Postextubation care and counseling reduces adverse airway-related outcomes. (b) Documentation of a difficult airway and management reduces subsequent adverse airway-related outcomes. (c) Registration with an emergency notification service reduces subsequent adverse airway-related outcomes.

Scientific evidence was derived from aggregated research literature and from surveys, open presentations, and other consensus-oriented activities.† For purposes of literature aggregation, potentially relevant clinical studies were identified *via* electronic and manual searches of the literature. The electronic search covered a 37-yr period, from 1966 through 2002. The manual search covered a 60-yr period, from 1943 through 2002. More than 3,000 citations were initially identified, yielding a total of 1,106 non-overlapping articles that addressed topics related to the 30 evidence linkages. After review of the articles, 538 studies did not provide direct evidence and were subsequently eliminated. A total of 569 articles contained direct linkage-related evidence. Of these, 255 articles either used or included subjects with difficult airways.

† Readers with special interest in the statistical analysis used in establishing these Guidelines can receive further information by writing to the American Society of Anesthesiologists: 520 North Northwest Highway, Park Ridge, Illinois 60068-2573.

Table 4. Summary Statistics for Commonly Reported Outcomes*

Evidence Linkage	No. Studies†	Successful Intubation, %	First Attempt Success, %	Mean No. Attempts	Mean Time to Intubation, s	Airway Obstruction, %	Hypoxemia, %	Sore Throat, %	Cough, %	Laryngospasm or Bronchospasm
Awake intubation										
Difficult airway	19	81–100 (9)	80–100 (4)	1.1 (1)	52–192 (3)	—	10–14 (4)	25 (1)	10–21 (3)	3 (1)
Nondifficult airway	5	80–88 (2)	40 (1)	—	—	—	—	17 (1)	64 (1)	—
Rigid laryngoscopic blades of alternative design or size										
Difficult airway	7	63–100 (2)	—	—	—	—	—	—	—	—
Nondifficult airway	8	—	—	—	—	—	—	—	—	—
Fiberoptic-guided intubation										
Difficult airway	43	87–100 (21)	75–80 (3)	1.1–1.3 (2)	24–406 (12)	—	10–30 (4)	41 (1)	21–25 (2)	—
Nondifficult airway	26	88–100 (13)	85–95 (7)	1.0 (1)	16–220 (20)	—	—	39–53 (2)	6–64 (2)	—
Intubating stylet or tube changer										
Difficult airway	10	78–100 (6)	—	—	41 (1)	—	—	—	—	—
Nondifficult airway	10	94–100 (7)	75–93 (4)	1.1–1.2 (2)	17–91 (6)	—	—	6 (1)	—	—
Lighted stylet or light wand for intubation										
Difficult airway	10	79–100 (8)	80–86 (2)	1.1–2.2 (2)	19–33 (3)	—	—	6–20 (2)	—	6 (1)
Nondifficult airway	22	63–100 (16)	67–100 (10)	1.1–2.0 (4)	17–107 (12)	—	7 (1)	10–49 (8)	—	—
Laryngeal mask airway										
Difficult airway	32	80–100 (5)	90 (1)	2.4 (1)	—	—	6 (1)	10 (1)	4 (1)	—
Nondifficult airway	162	82–100 (49)	67–100 (40)	1.0–1.4 (6)	7–49 (15)	2–36 (5)	1–13 (15)	7–71 (33)	2–32 (14)	2–60 (11)
Intubating laryngeal mask airway										
Difficult airway	41	30–100 (13)	20–100 (9)	1.3 (1)	20–168 (5)	—	5–13 (2)	33–67 (2)	—	—
Nondifficult airway	25	67–100 (21)	34–100 (16)	1.1–1.6 (4)	10–86 (5)	—	6 (1)	14–21 (2)	6–28 (2)	3 (1)
Emergency laryngeal mask ventilation										
Difficult airway	3	98 (1)	—	—	—	—	—	—	—	—
Esophageal tracheal Combitube ventilation										
Nondifficult airway	13	94–100 (5)	38–92 (3)	1.2 (1)	25–27 (2)	—	—	16–48 (3)	—	—
Capnography or end-tidal CO ₂ detection										
Difficult airway	4	89–100 (3)‡	—	—	—	—	—	—	—	—
Nondifficult airway	22	66–100 (9)‡	—	—	—	—	—	—	—	—
Other confirmatory tests (i.e., esophageal detector, self-inflating bulb)										
Nondifficult airway	9	50–100 (8)‡	—	—	—	—	—	—	—	—
Awake endotracheal extubation										
Nondifficult airway	7	—	—	—	—	5–22 (2)	5–34 (4)	36–68 (2)	6–85 (4)	3–8 (4)
Awake laryngeal mask airway removal										
Nondifficult airway	12	—	—	—	—	1–10 (3)	1–36 (6)	—	5–52 (7)	1–33 (5)
Supplemental oxygen after extubation by mask, blow-by, or nasal cannulae										
Nondifficult airway	16	—	—	—	—	—	1–19 (10)	—	—	—

* Range of outcome values reported by the reviewed studies for evidence linkage (number of studies reporting data for the respective outcome). † The number of studies reported in this column represent the total number of studies for each evidence linkage. ‡ These percentages represent detection of proper intubation.

A directional result for each study was initially determined by a literature count, classifying each outcome as either supporting a linkage, refuting a linkage, or neutral. The results were then summarized to obtain a directional assessment of support for each linkage, with the intent of conducting meta-analyses where appropriate. Summary statistics for selected outcomes commonly reported in the literature are shown in table 4. These descriptive statistics separate the reported outcome data for difficult and nondifficult airway subjects.

There was an insufficient number of acceptable studies to conduct a meta-analysis for the difficult airway.[‡] However, two evidence linkages contained studies pertinent to the Guidelines with sufficient statistical information to conduct formal meta-analyses. These two linkages were as follows: linkage 2 days (preanesthetic preoxygenation for 3 min *vs.* 4 maximal breaths) and linkage 6b (supplemental oxygen delivery by mask, blow-by, or nasal cannulae after extubation of the trachea).

Weighted mean effect sizes were determined for continuous outcome measures, and Mantel-Haenszel odds ratios were determined for dichotomous outcome measures. An acceptable significance level was set at $P < 0.01$ (one-tailed). Tests for heterogeneity of the independent studies were conducted to assure consistency among the study results. DerSimonian-Laird random-effects odds ratios were considered when significant heterogeneity was found. To control for potential publishing bias, a "fail-safe N" value was calculated. No search for unpublished studies was conducted, and no reliability tests for locating research

[‡] Meta-analytic data for nondifficult airway patients can be obtained by writing to the American Society of Anesthesiologists.

results were performed. For time to desaturation, the weighted mean effect size was $d = 1.57$ (CI, 0.98-2.14) for linkage 2 days (preanesthetic preoxygenation for 3 min *vs.* 4 maximal breaths). For reduced frequency of hypoxemia, the fixed-effects odds ratio was 5.98 (CI, 3.16-11.31) for linkage 6b (supplemental oxygen delivery by mask, blow-by, or nasal cannulae after extubation of the trachea).

Interobserver agreement among Task Force members and two methodologists was established by interrater reliability testing. Agreement levels using a kappa (κ) statistic for two-rater agreement pairs were as follows: (1) type of study design, $\kappa = 0.64-0.78$; (2) type of analysis, $\kappa = 0.78-0.85$; (3) evidence linkage assignment, $\kappa = 0.89-0.95$; and (4) literature inclusion for database, $\kappa = 0.62-1.00$. Three-rater chance-corrected agreement values were as follows: (1) study design, $Sav = 0.73$, $Var(Sav) = 0.008$; (2) type of analysis, $Sav = 0.80$, $Var(Sav) = 0.008$; (3) linkage assignment, $Sav = 0.93$, $Var(Sav) = 0.003$; and (4) literature database inclusion, $Sav = 0.80$, $Var(Sav) = 0.032$. These values represent moderate to high levels of agreement.

The findings from the literature were supplemented by the opinions of Task Force members, as well as by surveys of the opinions of 50 anesthesiologists selected as consultants on the basis of their recognized interest in airway management. The κ statistic was used to obtain a quantitative measure of agreement among consultants. Consultants exhibited strong agreement ($\kappa \geq 0.75$) on the potential beneficial effects of the following activities: conduct of the airway history and physical examination, advance preparation of the patient and equipment, formulation of strategies for intubation and extubation of the difficult airway, and provision of follow-up care.