Guidelines Based on the Principle “First, Do No Harm”

New Guidelines on Tracheal Tube Confirmation and Prevention of Dislodgment

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In 1992 ECC experts thought the “gold standard” to confirm correct tracheal tube placement was the multiple, time-honored physical examination criteria:

- See the tube passing through the cords.
- Hear proper sounds when checking 5-point auscultation.
- See the chest expand with each ventilation.
- Note improvement in the level of oxygen saturation.
- See vapor condense in the tube with ventilations.

The experts and clinicians working on recommendations in 1992 rejected several proposals to add secondary confirmation techniques to the resuscitation guidelines. They did not recommend qualitative single-use devices that measured expired CO2, largely because of expense. They did not accept the inexpensive esophageal detector device (EDD), in large part because the evidence revealed that errors still occurred with them. Continuous quantitative expired CO2 measurements as a method to detect tube dislodgment were not even mentioned 8 years ago.

The original goals of secondary confirmation techniques were to

- Always identify and remove all esophageal intubations (100% sensitivity to failed intubations)
- Never remove a tracheal tube that is in the trachea (100% specificity to successful intubations).

In 1992 no secondary detection technique performed at this level, and none do now (2000). The evidence the experts used to support the decision to not recommend secondary confirmation devices was their strong confidence in a flawed assumption: the hallowed confirmation by physical examination criteria simply could not be improved (Level 8 evidence). In addition, no one asked the question, Does discovery of a tracheal tube in the esophagus in the Accident and Emergency Department or the postanesthesia recovery area indicate an original esophageal tube placement, or an unrecognized tracheal tube displacement that took place after proper tracheal intubation? Guidelines on how to prevent tracheal tube dislodgment were nonexistent. The 1994 ACLS textbook contained only a 2-word recommendation: “secure tube.”

Between 1992 and 2000, however, an increasing body of information about high rates of errors in medicine began to accumulate.1-3 Resuscitation leaders became concerned that patients under their care were experiencing undetected esophageal intubation and undetected tracheal tube dislodgment at a frequency far higher than commonly recognized. The “evidence” that raised these suspicions was indirect and retrospective. Esophageal intubation and tube dislodgment are perceived to be uncommon events. This frequency is so low that a single practitioner may never be involved personally with such an event. In many locations quality assurance committees review these episodes if they learn about them. Quality assurance records, however, are sealed and not available for discovery.

Teachers and practitioners in residency training programs in anesthesiology, emergency medicine, and paramedic programs at academic medical centers hear about and know of these problems locally, often because they were the professionals who discovered the out-of-place tube.4 This experience in teaching and training programs leads to widespread suspicion that the true rate of misplaced or dislodged tracheal tubes is much higher than ever suspected.5-10 These complications are extremely serious—if unrecognized they inevitably result in death or severe neurological injury. Most importantly, these are preventable tragedies that devastate families and friends and cut short many young lives.

Recent studies on errors in medicine contend that an accepted tenet of the culture of healthcare providers is to cover up or obscure errors like unrecognized esophageal intubations.2,11 In terms of open, candid discussions oriented toward remedies, the medical culture lags far behind other professional groups who must maintain life or death skills.14,15 Avation pilots have been the most common comparison group with doctors.14,15

In the United States any discovered esophageal intubation or tracheal tube dislodgment often results in the filing of a wrongful death or injury lawsuit against the responsible physicians, institutions, or other healthcare providers. Reviews of databases of legal cases and filed lawsuits are one way of getting a sense of how often these events might be occurring. Informal reviews of some of these private databases by the authors confirm the existence of many lawsuits.
filed because tracheal tubes are misplaced originally or dislodged after initial proper placement.

One subspecialty society in the United States has established a unique and highly valuable source of information on malpractice claims against anesthesiologists, called the American Society of Anesthesiology (ASA) Closed Claims Project, established by Professor Fred Cheney of the University of Washington in the mid 1980s. The cases in this database are serious misadventures that occur even in the rigidly controlled environment of the operating room or in preoperative or postoperative locations. The cases involve a myriad of problems: teeth and jaw injuries, nerve injuries, problems in gas delivery, equipment failures, eye injuries, and even cases in which operations have been performed during persistent "awarness/awake states." The ASA reports the most damaging events, such as unrecognized esophageal intubations or unrecognized tube dislodgment during the operation, transfer, or movement by the patient.

One of the most admirable features of this ASA project has been the willingness of departments of anesthesiology to identify, analyze, and report these errors. Each event is classified into preventable versus not preventable, and investigators make considerable efforts to determine what was the most likely cause of the event: operator use error, operator maintenance error, equipment design, equipment malfunction, and predictable and unpredictable component failures. This allows open discussion of corrective measures, redesigns, or even new devices. All actions attempt to move the specialty closer and closer to the zero-risk goal.

Of great help to anesthesiology have been evaluations and discussion of whether some new monitoring device or technique, if used in the adverse event cases, would have prevented the mishap. For example, as long ago as 1974 to 1988—4 years before the concept was rejected at the 1992 Guidelines Conference—the ASA examined 1097 claims and concluded that monitoring devices would have completely prevented 32% of the morbidity and mortality. Pulse oximetry and capnometry were the 2 monitoring techniques judged most useful; taken together they could have prevented 93% of the preventable mishaps.

Historically the ASA has been the major leader in the movement to commit to the concept "first, do no harm." To use positive terminology, experts and advisors now speak of the need to "create a zero-risk environment" in which to conduct anesthesia. Over the past 2 decades these principles have coalesced and blended with the principles of the human-engineering/human-factor design movements. The principles include a rejection of the quality assurance model of "find the bad apple; eliminate the problem." Furthermore, we now have widespread acceptance of the concept that errors in medicine must not be attributed to "bad or unskilled or ignorant practitioners, who never learned and never remember." Instead, we must view errors in medicine, as in the aviation industry and other public safety organizations, more as system errors or defects in the practice culture and environment than as defects in the practitioners.

The practitioner makes an error because the design of the equipment or the design of the immediate practice environ-
ing the zero-risk concept: 2-step AEDs will experience far fewer operator failures than 6-step devices.

Despite the imperative to make medical devices “operator-proof,” it is impossible to take the operator or practitioner completely out of the picture. There always remain significant skill requirements in resuscitation, with the psychomotor skill of tracheal intubation looming as the highest challenge for most practitioners. How can responsible individuals make the practitioner error-proof or mold the individual into a zero-risk performer?

In March 2000 the British Medical Journal devoted parts of several issues to the topic of error in medicine. Leaders in this field place great hope on high-fidelity simulators that can train multiple responders to coordinate and work together as a team during resuscitative efforts. Many thoughtful innovations under way in training simulators are integrating sophisticated sensors and pressure gauges with interactive, virtual reality programs. The programs can now handle the problem of reacting not to predetermined instructions but to the actions and decisions of the trainee.

At the international Guidelines 2000 Conference these concepts and principles were ubiquitous. The experts, clinicians, and other participants encountered numerous areas in which objective evidence is weak or absent and fails to support evidence-based recommendations. The experts and resource people often invoked the basic principles of “first, do no harm,” “accept only zero-risk interventions,” and “never commit type II (false-negative) diagnostic errors.”

The most dramatic example of this approach was provided by an excellent prospective study of out-of-hospital, paramedic-performed, pediatric tracheal intubation. The study, led by Marianne Gausche and her colleagues in the Los Angeles County EMS system, California, USA, reached the surprising conclusion that in this particular system, with well-trained but inexperienced paramedics traveling short distances (5-minute transport interval) to receiving hospitals, intubation did not improve survival over bag-mask ventilation.

Other results in this study hit the supporters of out-of-hospital provision of advanced resuscitation care with stunning force. Out of 177 pediatric patients who were intubated and transported to the Emergency Department for further care, a total of 15, or 8% (15/177), were determined to have either esophageal intubation or unrecognized dislodgment of the tracheal tube sometime between the original intubation attempt and placement on the Emergency Department stretchers. Faced with this data, the Medical Director of the Los Angeles EMS system, Sam Stratton, took appropriate action, directing that all equipment for pediatric intubation be removed from the emergency vehicles. Authorization for the medics to attempt pediatric intubation was withdrawn. This incident provides an excellent example of taking the necessary, and highly controversial, actions needed to create a zero-risk intervention. Drs Gausche and Stratton merit our admiration.

How should this data on esophageal intubation be interpreted? Esophageal intubation and unrecognized dislodgment of a tracheal tube are mortal errors. In their conscientious efforts to help their patients, some paramedics commit an act that contributes directly to the death of their patient. The advanced intervention of tracheal intubation combined with the diagnostic skills of the medics (to detect tube misplacement) is far from being a zero-risk action.

The chief investigators from the Los Angeles study first presented their results in May 1998 at the Scientific Assembly of the Society for Academic Emergency Medicine. At that same conference investigators from Orlando, Florida, presented an equally disturbing abstract of high rates of out-of-hospital paramedic esophageal intubations for adults and children. For 8 months physicians evaluated all patients arriving at a regional trauma center with a tracheal tube inserted by out-of-hospital personnel. On arrival of patients at the Emergency Department, physicians discovered a stunning 25% of the patients (27 patients out of 108) to have improperly placed tracheal tubes. For 18 of the 27 the tube was in the esophagus; in 9 of the 27 the tube was above the vocal cords. The investigators considered this incidence of out-of-hospital, unrecognized, misplaced tracheal tubes excessively high. They started a reevaluation of their out-of-hospital training and protocols, but they have not yet published their complete results.

These 2 studies, reported in national newspapers, stimulated a strong sense of urgency at the Guidelines 2000 Conference. Here was an intervention that clinicians and practitioners regarded as definitive therapy for victims of cardiopulmonary emergencies, but it was beginning to appear to be a dangerous weapon in the hands of out-of-hospital ACLS personnel. Although tracheal intubation attempts always had the potential to harm the patient, this was the first indisputable evidence that these iatrogenic tragedies were taking a toll.

What Is the Solution?

The attendees at the Guidelines 2000 Conference shared the intense concern of many that ACLS providers may be inadvertently causing death from esophageal intubation or undetected tube dislodgment. Everyone was receptive to proposals to add recommendations to the guidelines to reduce these adverse events. The available techniques include the following:

- **Qualitative end-tidal CO₂ detectors** that undergo a color change when expired CO₂ passes across the detector surface

- **Quantitative end-tidal CO₂ measurement devices called capnometers.** These monitors digitally display a single numeric value for the highest level of expired CO₂ reached during expiration, a process called capnometry. Cutoff levels identify when the tube end is in the trachea versus the esophagus or hypopharyngeal area.

- **Quantitative capnographic waveform monitors** that provide, in a process called capnography, a continuous display of the amount of CO₂ expired over time. The waveform of patients with a pulse and with the tracheal tube in place shows a very distinct pattern of CO₂ level during expiration from dead space, the alveoli, and then inspiration. In patients with cardiac arrest, however, use of expired CO₂
Endorsement of either of these devices was slow because the clinical expectation was for devices that were virtually 100% accurate with all uses. Each of these confirmation techniques, however, has significant accuracy problems. End-tidal CO₂ measurements, for instance, are relatively inaccurate in patients without blood flow or a beating heart. The CO₂ is simply not delivered to the lungs for exhalation. The more common error, therefore, is a false-positive error in which the operator is led to think the tube is in the esophagus. The operator’s response should be to remove the tracheal tube unnecessarily, which is a type I or false-positive error.

The EDDs, however, are much better for the cardiac arrest patient, because the measurement does not depend on a beating heart. There are, however, a number of situations in which EDDs will indicate to the operator that the tube is in the trachea when it is not. This is the dreaded “type II or false-negative error,” in which the diagnostic test looks for “disease,” in this case an esophageal intubation. The accompanying editorial on the pulse check discusses the significance of committing a false-negative (consequence can be death) versus a false-positive (consequence can be unnecessary treatment) error. In people with marked obesity or chronic lung disease with chest hyperexpansion or in victims in whom the stomach was filled with air during CPR, EDDs will often rapidly reexpand, indicating tube placement in the trachea. This finding, however, is a false-negative result, leading the operator to think the tube is in the esophagus, often leading to severe consequences.

Obviously perfection in terms of secondary confirmation of endotracheal intubation is unlikely. Both types of devices have significant rates of false-positives and false-negatives. Capnographic waveform monitors are the method of choice, but the devices can run to hundreds of dollars, posing a distinct disadvantage in some settings. In general, an algorithmic approach using several techniques is being recommended for prehospital care. Distinguishing clinical features are the presence or absence of a pulse.

- If a pulse is present, rely on the colorimetric, qualitative CO₂ techniques.
- If a pulse is absent, use the colorimetric CO₂ device. But if the device shows no color change, add the test of the EDD.

No air rush with positive suction indicates that the tracheal tube is in the esophagus—therefore reintubate. Air rush with no suction indicates that the tube is in the trachea—therefore secure the tube.

Evidence is just beginning to accumulate about securing the tube in place to prevent dislodgment. We lack high-level evidence because the problem is so difficult to study. Some work suggests a surprisingly large amount of tube movement with minimal head and neck flexion and extension. Anesthesiologists have been vocal and adamant about their traditional techniques of tape-and-string to secure the tube, contending an error-free history. A respected textbook of emergency medicine has only 1 illustration on this topic; it features line drawings of how to tear and split adhesive tape, with no mention of the many commercial tube holders available. At this time the Guidelines 2000 Conference can make only a Class IIB recommendation for the use of commercial tube holders, especially for intubations in the out-of-hospital setting. Despite the large number of manufacturers of tracheal tube holders, none supplies objective evidence comparing holder versus no holder or one brand of holder versus another.

Recent legal and clinical trial data plus observational epidemiology, however, create a high level of suspicion that the problem of tracheal tube displacement may be devastatingly large.

Summary
In summary, this editorial and the one on pulse check point out another area in which a total reliance on evidence-based guidelines may do our patients a disservice. The debate over dropping the pulse check hinged less on the strength of the evidence and more on the widespread clinical principle of fear of false-negative errors. The discussion of secondary confirmation of tracheal tube placement also lacks a strong base of evidence that identifies the one best technique of tube confirmation for patients with a pulse versus those without a pulse. The principles of the zero-risk intervention and first, do no harm come into play in this situation. We must deal with the growing awareness of the fact that tracheal intubation is not only a potentially lethal intervention but now is also a confirmed lethal intervention, and at a much higher death rate than has ever been suspected. Factors that contribute to the transformation of the tracheal tube from a life-saving to a death-causing intervention are being identified by honest and open researchers. National societies in emergency medicine are responding appropriately. We strongly recommend shifting from making an evidence-based recommendation to instead making a principle-based recommendation—killing our patients is unacceptable; we must act on the widespread concept regarding errors in medicine. We must adopt zero-risk interventions in all possible situations.

References


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