The role of institutional review boards

As a researcher and institutional review board (IRB) member, I read the article, “Protecting Patients During Clinical Research” (February 2004:53-59), with great interest, and I am appreciative of the exemplars the author gives as potential pitfalls in the clinical setting. However, I disagree that the IRB is the first level of protection of a patient’s rights during clinical research.

The IRB is only one of the safeguards (albeit one of the most important institutional safeguards) for protection of patient rights. The first, and most important, safeguard is the ethics of the researcher. A researcher’s ethics carry a project from identification of the topic to publication of the study.1 In addition, researchers with high ethical standards do not view the IRB in an adversarial context, but rather as a double check for the protection of human subjects. I have undergraduate student research assistants, and if they learn nothing else during the course of their study with me, they learn the application of ethical standards during research in the clinical setting. Learning by example; it is just that simple.

A second of item of concern in the article is the response to a dilemma in Table 5:

Scenario: Karen, a nurse on your unit, states that she will be collecting data from her patients and their medical records for a “school project.” When asked, she states she doesn’t think her protocol needs approval from the institutional review board and that she is under a deadline.

Response: Immediately tell Karen that this violates federal law and hospital policy. Notify your nurse manager or advanced practice nurse to back up your position. Direct Karen to the coordinator of the institutional board for protocol review.

Telling someone they are in violation of federal law and hospital policy without further investigation could be uncomfortable and embarrassing for both parties. A better response might be to ask Karen to provide a written explanation of the project and a signed form from the instructor and nurse manager allowing Karen to collect the data. The nature of the project determines the need for IRB approval. If a written explanation of the project and signed form from the instructor and nurse manager are not available, phone calls could be made to obtain clarification. If the instructor and nurse manager are not immediately available, waiting for clarification would be the preferred option.

Thank you for sharing these aspects of clinical research with practicing nurses.

Reference
Low-dose steroid replacement in severe sepsis—response

In response to the Letter to the Editor by Doson Chua in the April issue (2004:16), I disagree with her statement that the use of steroid therapy is currently advocated for use in all patients with severe sepsis. A large, well-done, randomized clinical trial demonstrated that empiric use of steroids in patients with severe sepsis or septic shock was associated with a significant reduction in mortality. However, this benefit was limited to patients who failed to increase their cortisol levels by 9 in response to corticotrophin stimulation test. Among this group, there was a 10% absolute reduction in mortality when treated appropriately. The evidence therefore indicates (1) a corticotrophin stimulation test on all patients with severe sepsis or septic shock and then (2) empirically treating patients with severe sepsis or septic shock (50 mg hydrocortisone every 6 hours plus 0.1 mg of Flurinep twice daily). In patients with cortisol increases by less than 9 in response to the stimulation test (nonresponders), steroids should be continued for 1 week and then discontinued. Longer term use of steroids may cause increased morbidity.

Reference

Karen Aloe, RN, MSN, CCRN, CNS
Long Island, NY

Placement of endotracheal and tracheostomy tubes

I recently read the article, "Airway Management" (April 2004:93-96), and noticed that information related to depth of endotracheal tube (ETT) and tracheostomy tube (TT) suctioning was not addressed. It is still common practice for nurses to insert suction catheters until they meet resistance and then apply suction. The resistance felt is when the catheter meets the carina or bronchial mucosa. Inserting a suction catheter to this point can cause negative consequences for the patient.

Alternately, some nurses insert suction catheters until resistance is met, and then pull the catheter back before applying suction. Unfortunately, meeting resistance and then “pulling back” before suctioning is not a solution. Research suggests that catheter contact rather than suction is responsible for mucosal damage. Studies in kittens have shown that inserting a catheter to resistance caused as much damage as insertion to resistance with the subsequent addition of suction. The effect of deep suctioning is tracheal mucosal damage, including epithelial denudement, hyperemia, loss of cilia, edema, fibrosis, and granuloma formation. This damage occurs when tissue is pulled into the catheter tip holes, and increases the risk of infection and bleeding for the patient. The purpose of suctioning is to remove secretions that are not accessible to bypassed cilia. Therefore, insertion of suction catheters only as far as the end of the placed ETT and TT has been recommended. Nurses may argue that though shallow suctioning appears to be less injurious to mucosa, it may also be a less effective method of removing secretions. However, there is no reason to suspect that mucociliary transport below the tip of the ETT or TT should function abnormally. Therefore, larger volumes of aspirates would be collected in shallow-suctioning. Once deep-suction is initiated, the resulting damage to cilia may necessitate the need for continued deep suctioning. When an adult patient is endotracheally intubated, the distal portion of the tube sits between 3 and 7 cm above the carina. In neonates, the end of the ETT is frequently placed just 1 to 2 cm above the carina. Therefore, suction catheters should be inserted to a predetermined length. Passing suction catheters no further than 1 cm past the length of the ETT or TT can avoid contact with the trachea and carina. Resistance should not be met. If resistance is met, the suction catheter should be withdrawn at least 0.5 cm before applying suction. There are various methods of predetermining suction catheter depth and these methods should be incorporated into protocols for practice.

References

Mary Frances D. Pate, RN, DSN
Portland, Ore
The author responds:

This reader brings up an important element of the suctioning procedure to which there is no consensus. The ideal suction catheter insertion depth through either an ETT or TT remains both an area of controversy and research interest. The reader is correct in that the adverse consequences of deep suctioning have been well described in the literature for many years. Animal research has demonstrated tracheobronchial trauma as a result of deep versus shallow suctioning. Limited data suggest that restricting suction catheter advancement to 1 cm beyond the tip of the artificial airway does not compromise secretion removal effectiveness.

Clearly, mechanical trauma to the airway and mucosal surface is not just related to the suction catheter insertion depth, but also suctioning frequency, suction pressure levels used, ETT or TT movement, positive pressure effects of mechanical ventilation, and, to a lesser extent, suction catheter tip design, as most suction catheters in use today have incorporated safety features to minimize risk of tissue trauma when suction is applied. Van de Leur and coworkers recently studied 383 adults requiring endotracheal intubation randomized to either minimally invasive (29-cm suction catheter) or routine (49-cm suction catheter) catheter suctioning. They found no difference in the suction methods relative to duration of intubation, intensive care unit stay, intensive care unit mortality, and incidence of pulmonary infection. Suction-related adverse events (increased pulse pressure rate, decreased saturation via pulse oximetry, blood in mucus, and systolic blood pressure increase) occurred more frequently with routine deep suctioning versus shallow suctioning. In another recent study of 27 high-risk infants randomized to either shallow or deep ETT suctioning, there were no significant differences between the 2 methods in either heart rate and oxygen saturation before, during, or after ETT suction.

The vast majority of studies on this subject have focused on infants and neonates receiving ventilation. Spence and coworkers conducted an extensive literature search of controlled trials using random or quasi-random allocation of neonates receiving ventilatory support via an ETT to either deep or shallow endotracheal suctioning. They found that there was no evidence to conclusively answer the question as to whether shallow suctioning is preferred over deep suctioning in neonates and infants, and further high-quality research would be required. Given the published and anecdotal evidence of adverse effects of deep suctioning, this type of proposed study would ethically only be considered when the standard practice includes deep suctioning technique.

Indeed, as noted by other researchers interested in suctioning techniques and airway management, collaborative, research-based policies and procedures must be developed and implemented to ensure best practices for intubated patients. There are instances when deep suctioning may be reasonable such as the use of directional-tip catheters for suctioning the left main stem bronchus. Several suction catheter manufacturers have added depth markers along the catheters (both open and closed suction catheter systems) to aid clinicians who wish to limit insertion depth. Many hospitals utilize pre-measured suction catheter depth guides or cards at the bedside. This may be particularly helpful with neonatal and pediatric ETTs and TTs. Until a more definitive answer to this question is known, the available evidence would favor avoiding routine deep suctioning practice.

References


Robert E. St. John, RN, MSN, RRT, CCRN, CS
St Louis, Mo
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Mary Frances D. Pate

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