Contributing Factors to Patient Participation in Clinical Anesthesia Research

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Abstract

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It would be ideal to be able to identify a formula for successful enrollment in clinical anesthesia research. From our experience, the enrollment phase of the clinical trial is the most difficult part of the study. There are many unique challenges that anesthesia clinical research faces that contribute to making the enrollment phase complicated. First of all, anesthesiologists are not primary care doctors, so they must rely on other physicians to make up the patient population in the study. Secondly, in many cases consent for anesthesia research must be made on the same day of surgery, which is not ideal, but realistic. Lastly, most anesthesia research is not something you can advertise or patients are not actively looking for clinical studies in this field , so the investigator must have an efficient and effective screening/consent process in order to enroll the amount of subjects needed for the study.

The first challenge in clinical anesthesia research is finding the patient population. The investigator has to use patients from other physicians to make up the study population. The patient does not have the same trust and familiarity with the anesthesiologist as the clinical researcher as they would if their surgeon or internist was the study investigator. Many patients first response when approached to participate in anesthesia clinical research, is “does my surgeon/doctor know about this”. Patients want to feel secure that their surgeon/physician approves of the clinical study. However, some ethicists believe although patients preferred having the endorsement of their physician or surgeon, such advice is often interpreted as coercive. It is beneficial to have the surgeon/physician involved in the screening/consent process, no matter how limited it may be. Enrollment can be more effective if the surgeon/physician first introduces the study to the patient. In some of our experiences, patients appear more open to being approached about participation in a clinical trial when it is first discussed in the office of their surgeon/physician during the pre-operative office visit.

The next challenge is time. As more medical centers and hospitals are moving toward increasing same day admission (SDA) surgeries and outpatient surgeries, the anesthesiologist’s first meeting with the patient most likely is in the holding area just prior to their surgery. Many medical ethicists oppose obtaining consent for research on the day of surgery ($_1$). Patients presenting to the hospital on the day of their surgery may have considerable anxiety, making this a less than ideal place for obtaining informed consent. The Canadian National Council on Bioethics in Human Research has argued that any attempt to obtain a research consent on the day of surgery may be intimidating, coercive and a breach of the principle of autonomy ($_2$). However in reality, same day consents are necessary. Since anesthesiologists are not dealing with their own patients, they must rely on the surgeon’s/physician’s cooperation to provide amble notice of potential patients for enrollment if consent is to occur prior to admission to the hospital. Same day consent for research is acceptable if it is presented in an educational, non-intimidating, and open format. The patient should be comfortable with the explanation of the clinical

trail; should feel free to ask questions; and understand that they have the autonomous decision of their participation in clinical research. From past experiences, it is best to approach the patient as soon as they arrive to the admission area and when they have their family there for support.

Another challenge to the anesthesia researcher is awareness about the clinical research. In many clinical trials, patients are aware of research studies due to advertisement and active searches by patients to find particular studies. For example, high cholesterol studies are popular and are frequently advertised in the media. This is not appropriate for the majority of anesthesia trials so the investigator must come up with highly effective methods of informing potential study patients about the clinical trial and do so in a relatively short time frame. This is where an effective and open communication with the surgeon/physician and their office staff is of great importance. They are the ones that know first about the potential patients for the anesthesia research. A means for the communication of potential patients between these two groups is an important factor in enrolling patients. This can be daily OR schedule checks, involving the surgeon's/physician's staff in identifying potential patients, or other cooperative methods.

Despite these challenges, enrollment does occur and clinical trials are completed. But to what degree do certain factors contribute to the success of enrolling patients in clinical anesthesia trials. Is it the time factor? Would more patients enroll in an anesthesia trial if they had more time in the consent process? Or is it the trust factor? Would more patients enroll in an anesthesia trial if they knew the anesthesiologist and had more of an established patient-physician relationship as they have with their physician/surgeon? Or is knowledge and awareness of anesthesia clinical studies the key to successful enrollment? We propose to look at the contributing factors to patients participation in clinical anesthesia research. A questionnaire will be given to patients that are approached to participate in a clinical anesthesia research study. The questionnaire will ask the patient to rate how certain factors affect their decision to participate in an clinical study. This can assist in the determination of the most effective and efficient methods in obtaining informed consent for anesthesia clinical research and having successful enrollment in a clinical trial.

Are you interested in participating in a multicenter study investigating the contributing factors to patient participation in clinical anesthesia research? If so, please contact Raquel Reyna, R.N., B.S.N., research coordinator at Baylor College of Medicine in Houston.

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