Same-Day Consent for Regional Anesthesia Clinical Research Trials: It's About Time

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GLOSSARY

COVID-19 = coronavirus disease 2019; **ICU** = intensive care unit; **NHS** = National Health Service; **PAC** = preoperative assessment clinic; **REB** = research ethics board

Coronavirus disease 2019 (COVID-19) has changed the way anesthesiologists engage and interact with patients. As we hopefully approach the backend of this crisis, plans for the resumption of "nonessential" anesthesia services, including providing anesthesia for elective surgeries, reopening of anesthesia preoperative assessment clinics (PAC), and recruiting for regional anesthesia clinical research trials, will take shape. The COVID-19 pandemic has, however, highlighted a significant challenge in the current approach to research and the advancement of scientific knowledge in the regional anesthesia field: the perceived need to obtain consent to participate in such research in advance of the actual day of surgery. Notwithstanding the low-risk nature of participation in most regional anesthesia clinical trials, subject recruitment on the same day as surgery is often prohibited by local research ethics boards (REB) due to their concerns regarding patient autonomy and perceptions of patient vulnerability immediately before surgery that could impact the voluntary nature and the rigor of the informed consent process. In many centers, the anesthesia PAC has long served as the sole permissible and fertile ground for subject recruitment to clinical research, presumably ensuring fully informed consent to participate in a clinical trial in the absence of any undue duress and facilitating the establishment of a mutually trustful relationship. With the COVID-19–related suspension of in-person assessments in anesthesia PACs across most academic centers, recruitment for ongoing regional anesthesia clinical research trials has come to an abrupt halt and brought the long-standing controversy of same-day informed consent for low-risk clinical trials squarely back to the fore.

The widespread REB concerns regarding same-day informed consent for participation in regional anesthesia research trials have not been supported in the current literature. Even though anxiety in the face of impending surgery is a normal human reaction, patients are still presumed to be capable to continue to consent or to revoke consent to surgery while they wait to enter the operating room. There is no evidence that carefully conducted assessments of capacity to understand information pertaining to a research study and to appreciate how a choice to participate or not would apply to them cannot be performed in this period. There is no existing literature to suggest that patients are so vulnerable during this period that they must be systematically protected by prohibiting any discussion of potential participation in research in the immediate preoperative period. Arguably, such a systematic prohibition is ethically problematic in that, on its face, it appears paternalistic and can deny patients the benefits of research participation. The anticipation of a second wave of COVID-19 and the high likelihood of future pandemics from other emerging pathogens requires a more rigorous examination of such REB assumptions as prohibiting same-day consent to participate in regional anesthesia research risks stymying research and growth of this important and innovative field and fail in its goal to benefit patients in the perioperative period.

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ETHICAL TENETS AND INTERNATIONAL GUIDELINES

The 1964 Declaration of Helsinki outlined the tenets of informed consent: competency, disclosure, autonomy.[1] To ensure autonomy, subjects must offer their participation voluntarily, specifically, without any element of force, fraud, deceit, duress, or coercion. These tenets remain the pillars on which clinical research involving humans is founded and inform the respective Canadian and American Anesthesiologists' Society's guidelines for the ethical consult of clinical research.[2,3] Despite adaptations and updates over several decades, a single truth has prevailed: consent is paramount and, as with treatment, no research can occur without consent.

Chief among the roles of REBs is to ensure the consent process is rigorous and the autonomy of clinical research participants is respected. While the meaning of consent is both uniform and clear, that is, research participants must be capable of decision-making, fully informed, with ample time for consideration of options without coercion, and their choice must be respected,[1] what constitutes ample time is not as clearly defined. The World Health Organization states that "subjects must be given ample opportunity to enquire about the details of the trial… sufficient time, determined by the patient's health condition."[4] The Tri-Council Policy Statement, representing Canadian standards for ethical research involving humans, declares that "for consent to be informed, prospective participants shall be given adequate time and opportunity to assimilate the information provided."[5] In the United States, the American Medical Association is even less explicit, stating only that a valid consent process includes, "reviewing the process and any materials to ensure that it is understandable to the study population."[6] Locally, the University of Toronto's position on "ample time" is equally vague, only to consider "whether the contact person is known to the subject/authorized third party, has access to the patient information as part of their normal professional duties, or is able to assess capacity to consent."[7]

While there is currently no uniform explicit recommendation or absolute quantification for what constitutes adequate time for patient reflection before consenting to participate in a clinical research trial,[4,5,7] hospital-based REBs are also given some guidance regarding how much time is inadequate. Specifically, the Canadian National Council on Bioethics in Human Research likens the practice of same-day consent to intimidation, coercion, and breach of autonomy.[8] Ostensibly equating quantity with quality, some REBs have strongly discouraged same-day consent practices, instead opting for a minimum of 1–2 weeks for patient contemplation, irrespective of risk involved in study participation. Outside of North America, guidelines and recommendations on consenting practices for clinical research trials are similarly varied. The Table summarizes available recommendations from various international professional societies and government agencies regarding consent practices in the context of clinical research. Recommendations range from the oft-repeated requirement for "adequate" or "sufficient" time[9,10,13] to a more explicit demand for at least 24 hours for patient consideration.[11] A notable deviation is the proportionate approach to seeking consent for clinical trials advised by United Kingdom's National Health Service (NHS).[14] When seeking consent for patient participation in a clinical trial, the NHS recommends that "for research involving only minimal risks and/or little deviation from normal/standard clinical practice… it may be reasonable to accept a decision taken at the time of approach."[14] Additionally, the extent of information provided ought to be proportionate to the "nature and complexity of the research trial, risks, burdens, and potential benefits, the ethical issues at stake."[14]

Most physicians and surgeons meet with their patients on multiple occasions, affording these investigators time to identify, recruit, and enroll suitable research participants and obtain informed consent. However, specialties, such as anesthesiology, critical care, interventional radiology, and emergency medicine, have a varied pattern of practice and patient acquaintance that does not typically afford the luxury of time or, in many cases, delayed consent to research.[15] Indeed, the initial encounter between anesthesiologists and patients undergoing elective procedures routinely occurs on the day of surgery. Recognizing our specialty's unique practice patterns, the Canadian Anesthesiologists' Society's guidelines on the ethics of clinical research state that "preoperative consent for clinical research in anesthesia may be obtained after admission to hospital, either before or on the day of the scheduled surgery."[2] Yet an impasse is occurring in regional anesthesia with clinical investigators working in a time-limited perioperative system yet prohibited by REBs, both locally and otherwise, from consenting patients for clinical trials on the same day as surgery.[8,15]

THE QUESTION OF PATIENT VULNERABILITY AND NEED FOR PROTECTION IN PRACTICE

Concerns of inadequate patient comprehension, time for contemplation, and privacy, as well as undue duress, coercion, and anxiety, continue to undermine same-day consent for regional anesthesia clinical research trials. These concerns, however, have not been borne out in the literature. When consent is obtained on the same day as surgery, the vast majority of patients do understand the intent of the clinical anesthesia trials and recognize that participation

Table. International Recommendations for Same-Day Consent Practices

Country	Institution	Guidelines/Recommendations on Timing of Consent	Specifications for Low-Risk Trials
Australia	National Health and Medical Research Council (2018)[9]	"Adequate time should be allowed for prospective participants to understand and consider what is proposed and for their questions and expression of concerns to be addressed by those obtaining their consent."	"Proportionate to needs of participants, study risks, and ethical sensitivity."
Belgium	European Patient Forum (2016)[10]	"The patient must be given sufficient time to consider the decision."	"A common problem for patients is that they are often given *too much information at once* … it does not contribute to their understanding … or help in balancing the risks and benefits involved. Thus, a more *flexible and tailored approach* should be applied that allows individual needs to be met."
Denmark	National Videnskabsetisk Komité (2011)[11]	"The time for reflection depends on the nature of the trial. Basically, it should be at least 24 h."	"The time for reflection depends on the *nature* of the trial."
France	European Patient Forum (2016)[10]	"The patient must be given sufficient time to consider the decision."	"A common problem for patients is that they are often given *too much information at once* … it does not contribute to their understanding … or help in balancing the risks and benefits involved. Thus, a more *flexible and tailored approach* should be applied that allows individual needs to be met."
Ireland	Health Service Executive: Quality and Patient Safety Division (2013)[12]	"It is good practice where possible to seek the service user's consent to the proposed procedure well in advance, when there is time to respond to the service user's questions and provide adequate information." "Asking a service user to provide consent just before the procedure is due to start, at a time when they may be feeling particularly vulnerable, or seeking consent from someone who is sedated, in pain or anxious, creates doubt as to the validity of the consent."	"Where the research entails only minimal risk, it is sufficient if the research offers the prospect of benefits either to the participants directly or to the group which is the focus of the research and to which the participants belong." "Where the research poses more than minimal risk, it should … offer the prospect of direct benefits for the participants themselves and be *commensurate* with the level of foreseeable risk."
New Zealand	Auckland District Health Board (2018)[13]	"Sufficient time should be allowed for the patient to read the written information, and discuss this and any verbal information with whomever they wish."	"The *higher the probability of risk* or the greater the magnitude of harm, the *more care and detail in giving information* is required." "The patient must be informed of rare risks that are more likely because of their particular circumstances, or which would have greater significance for that particular patient, for example, the consequences of arm nerve damage for a carpenter."
United Kingdom	NHS Health Research Authority (2019)[14]	"There are no definitive guidelines or legislation regarding the appropriate amount of time (or minimum amount of time) that potential participants should be allowed to consider whether to take part in research or not. A proportionate approach (in a nonurgent scenario) means that for more complex or burdensome studies a longer time may need to be provided for potential participants to consider their decision than that provided for simpler studies involving lower risks…For research involving only minimal risks…it may be reasonable to accept a decision taken at the time of approach."	"A *proportionate approach* to seeking consent, that is, adopting procedures commensurate with the balance of risk and benefits, should always be adopted so that potential participants are not overwhelmed by unnecessarily lengthy, complex, and inaccessible information sheets but instead are provided with succinct, relevant, truthful information in a user-friendly manner that better promotes their autonomy." "The methods and procedures used to seek informed consent and the level of information provided should be *proportionate to*: -Nature and complexity of the research -Risks, burdens, and potential benefits -Ethical issues at stake"

Abbreviation: NHS, National Health Service.

is voluntary and that consent may be withdrawn at any time without consequence.[16,17] Patients are capable of digesting consent form documents and making informed decisions about research participation in thirty minutes or less.[16,18] Similarly, most patients feel that the perioperative setting offers adequate privacy for consent discussions.[16] Purported coercion of patients by their clinician investigators in the immediate preoperative setting has also been refuted[16,17]; 1 anesthesia study found that 97% of patients rated the preoperative setting as "ideal" for obtaining informed consent to participate in clinical anesthesia trials.[16]

The latter is most likely explained by patient preference for physicians with whom they will and/or must establish a relationship; accordingly, same-day consent by the responsible physician is likely superior to that by any surrogate.[18] Moreover, concerns of patient anxiety have not been realized as anesthesia researchers found no incremental increase in patient anxiety with same-day versus day-before recruitment and consent.[19] Finally, increasing the quantity of time for patient contemplation as a means to increase the quality of the informed consent process for regional anesthesia research has not been substantiated.[20]

Moreover, nowhere in medicine is the direct relationship between vulnerability, quantity of time for patient contemplation, and quality of consent more poignantly questionable than in the intensive care unit (ICU). Rarely are patients (and their substitute decision-makers) more vulnerable than when a person is admitted to an ICU with life-threatening illnesses. Nonetheless and until proven otherwise, ICU patients (or their substitutes) are deemed capable of making life-altering, and sometimes life-ending, and participation in research decisions in one or more moments of time.[21]

Furthermore, similar to academic regional anesthesiologists, emergency medicine and radiology clinician investigators have limited interaction with their potential study participants, often meeting on a single encounter with no opportunity to recruit and consent their patients in advance of that encounter. Recognizing these limitations, REBs allow for deferred, targeted, or staged consent in order for patients to participate in emergency medicine clinical trials.[22] While such urgent or emergent adaptations to the standard informed consent process are not justified for the elective perioperative setting wherein most regional anesthesia clinical trials occur, the same is not true for the radiology research experience. Indeed, low-risk radiology studies are generally approved for enrollment, recruitment, and consent on the same day as the radiological investigation or intervention.[23] The radiology ("X-ray") department may be unlike the operating room environment with respect to heightened patient anxiety; nonetheless, parallels are readily drawn between these 2 settings, including limited time and privacy, the potential for coercion, as well as the low-risk nature of many radiology and regional anesthesia clinical trials.

THE POTENTIAL SOLUTIONS

One workaround to ensure a robust consent process and patient protection, adopted by many anesthesia research programs, including those at the University of Toronto, has been the anesthesia PAC. Principally purposed to mitigate or optimize patient-related factors that may increase risk of perioperative complications, anesthesia PACs also function as the sole permissible venue (by our local REBs) for subject recruitment by research staff to low-risk clinical anesthesia research trials wherein subjects can provide informed consent days to weeks ahead of surgery. Unfortunately, however, this long-standing workaround is fraught with challenges in appropriate recruitment of participants in that patients attending PACs are likely to be sicker and thus ineligible for study inclusion than those fitter patients who do not attend PAC[15] and are more likely eligible for regional anesthesia clinical research. While the idea of coordinating with surgical colleagues to have healthy patients referred to PAC for the secondary purpose of study recruitment may be convenient for investigators, when balanced against creating inconvenience and lost income for patients, the use of hospital resources, health care dollars, and PAC time constraints, the idea quickly loses appeal.[16] Another makeshift solution is preadmission telephone calls, which have been used to introduce research protocols and initiate the informed consent process. However, many institutions consider these calls a violation of patient privacy as research personnel callers are not yet within the patient's circle of care.[15] Furthermore, scheduling of calls, anxiety provoked from unsolicited calls originating from the hospital, and constraints in time and manpower represent important ethical and logistical challenges.[18,24]

Conceivably, the COVID-19 pandemic may alter patient and provider views on telephone or videoconference as means to identify, recruit, enroll, and consent for research protocols. Though the pandemic has already rendered telemedicine more applicable and acceptable to patients and practitioners alike, whether or not it could or should penetrate clinical research programs to a similar degree, especially with respect to preserving the sanctity of privacy within the circle of care, will require ongoing consideration.[18,25] Ongoing requirements for universal masking inside of hospitals may further complicate recruitment and consent for clinical trials as clinician investigators must first establish a trustful relationship with potential research participants. While it removes the physical face-to-face component of a patient-physician interaction, 1 potential advantage of telemedicine is that it does allow unencumbered facial recognition and mutual awareness of affect. Thus, the persisting effects of telemedicine on clinical research programs beyond this pandemic are yet to be seen and require further study, including the patients' understanding and appreciation of disclosed information, perceptions of the consent process, concepts of ample time for decision-making, patient perceptions of coercion, and ability to make decision-making voluntarily and research recruitment rates.

Yet, our current understanding of patients' ability to provide same-day consent,[16,17] the lack of evidence of perceived or actual coercion, the perceived value of the fiduciary relationship with the physician performing the procedure,[16–18] and its low-risk nature would seem to mandate a reconsideration of the absolute prohibition on obtaining same-day consent for regional anesthesia clinical research instead of seeking to create more workaround solutions which may be more disruptive to patients and generate more patient anxiety. Most regional anesthesia clinical research trials primarily strive to improve and prolong pain control in the acute and subacute postoperative settings. In comparing the risk-benefit ratio for typical regional anesthesia clinical research trials versus that of other anesthesia subspecialties, it is evident that a proportionate approach to consent protocols is warranted.[14] Prohibiting same-day consent practices threatens systematic exclusion of patients otherwise fit and competent who may benefit from participation in regional anesthesia clinical research trials.

Ostensibly, the issue of same-day consent and its implications for clinical research trials would apply to all fields of anesthesia, but this is not necessarily true. Regional anesthesia is unique from other anesthesia subspecialties in its predilection for healthy and fit patients undergoing elective surgical procedures commonly in an ambulatory setting. In contrast, clinical trials in other anesthesia subspecialties (such as cardiac, thoracic, transplant, trauma, and obstetrical anesthesia) typically involve study of riskier interventions or care modifications with generally less resilient patients.

We recognize that consenting practices for regional anesthesia research trials vary across North American institutions, and consent on the same day as surgery is permissible at some institutions that house leading regional anesthesia research programs. However, our governing institution—the University of Toronto—publishes the second most scholarly journal articles in our specialty, second only to Harvard University,[26] yet the esteemed research hospitals affiliated with both the University of Toronto and Harvard University do not allow same-day consent for recruitment of patients to clinical anesthesia research trials. Such prohibitive regulations regarding same-day consent must not be the model for other institutions striving to develop their own regional anesthesia clinical research portfolios.

CONCLUSIONS

It behooves all regional anesthesia investigators to learn from the COVID-19 pandemic and identify opportunities for growth thereafter. The COVID-19 pandemic has unceremoniously exposed the arranged and strained marriage between our heretofore proliferative clinical regional anesthesia research program and our anesthesia PACs. During an unprecedented time in which clinical research and knowledge are driving day-to-day political, economic and health care decisions with monumental impacts locally, nationally, and globally, regional anesthesia research has been brought to a halt. While the issue of consent is not one to be taken lightly, the validity of same-day consent for low-risk anesthesia research trials has been widely supported.[8,15–19] Indeed, the NHS has responsibly acknowledged that the timing of consent can vary depending on the risk of study participation and that a universal "one-size-fits-all" approach to the timing of consent is not reasonable.[27] It is the process, rather than the time, that is the central to the validity of informed consent and safeguarding subject autonomy.[8] Prohibiting same-day consent for low-risk regional anesthesia clinical trials is an overly burdensome exercise for both clinical investigators and research staff. And so, while we continue to practice physical distancing, it is, in our opinion, high time to distance ourselves from such a prohibitive practice.

DISCLOSURES

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