Correspondence

Patient recruitment for clinical research

To the Editor:

Dr. Wong's letter[1] concerning patient recruitment for clinical research raises some interesting points concerning the time at which informed consent should be obtained and the implications of a "no exclusion" clause in a clinical research protocol.

We assume that the protocol was approved by the institutional ethics committee, although this is not stated in the letter. Were the three ocular block techniques for cataract surgery all commonly used? If so, they were not experimental techniques. If these assumptions are correct, the consent given by patients should have been only for collection and analysis of aggregate data for publication. Consent, either verbal or written, to have surgery performed under ocular block would have been obtained at the same time, and we are told that patients were made aware of the study by the surgeon. The informed consent for research, obtained shortly before anaesthesia and surgery, therefore refers to data collection concerning efficacy of the block rather than its performance.

We have never encountered a "no exclusion" clause in a study protocol and we are not sure what this could mean. The standard of care provided to patients must never be influenced by their decision to participate or not in a study protocol. Did all patients agree to participate and, if not, did they still have one of the three ocular blocks and their cataract surgery? The decision of the anaesthetist to proceed with the block in the patient described should have been based entirely on clinical criteria. We do not understand how postponement of surgery could have put the study at risk. The request of the patient, through his son, to proceed with the block and surgery was presumably because the patient wanted his vision restored and had nothing to do with the research protocol.

If there is a language barrier, the investigator, aided by an interpreter, must be satisfied that the patient understands what is entailed. The essential points to be covered include the reasons for the study, research techniques including randomization, anticipated benefits and consequences, foreseeable risks, maintenance of confidentiality of subjects, anticipated time commitment, and the right to withdraw from the study at any time and without penalty.[2] If the investigator has any doubts about the patient's ability to comprehend, the patient must not be enrolled and this should have no consequences for the patient's medical care.

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REPLY

I would like to thank Drs. Maltby and Eagle for their interest in the concerns I raised in regard to patient recruitment for clinical research.

The study protocol had been approved by both the university and hospital ethics committees on human experimentation. The study involved three ocular block techniques, one of which being an experimental approach. It involves, therefore, more than just data collection of established techniques. The nature and risks of the study were explained to the patients by the surgeon, who was a participating investigator, when they were seen at his office. On the day of surgery, these were explained to the patients again by the investigator-anaesthetist before written consent was signed.

The "no exclusion" term was used for the sake of brevity in my letter. The study involved day-care patients having cataract surgery at our Eye Care Centre (ECC). All patients were prescreened according to the criteria of the ECC with regard to their suitability for day-care surgery. The protocol stated that all patients who were accepted for ECC surgery would be suitable candidates for the study, and would not be excluded from recruitment because of age or medical problems, subject to patient consent. The "no exclusion" did not mean that all patients had to be in the study. The standard of care was not influenced by whether or not they participated, and this was made clear to the patients before seeking their consent. All patients gladly participated in the study. If the patient had refused to participate, a traditional technique (peribulbar block) would have been used, and he/she would not have been included in the study. It was the patient and his son who were keen on proceeding with the surgery and participating in the study, despite the assurance that withdrawing from the study would in no way compromise his care.

In regards to obtaining consent through an interpreter, all the points listed by Drs. Maltby and Eagle were explained ver-

bally to the patient, and stated clearly in the written consent form. It is only common sense that if the investigator has doubts about the patient's ability to comprehend, recruitment for study should not proceed.

My letter was intended not so much as to what information is required in an informed consent, but rather how the informed consent is obtained, especially from day-care surgery patients and in situations where there is a language barrier. In my case, the surgeon was a participating investigator who was in a good position to obtain informed consent. However, in other situations, attending surgeons, who are not participating investigators, may not be suitable for explaining the nature and risks involved. The move by many hospitals to preadmission clinics and same-day surgery creates a situation in which the investigator-anaesthetist may not be the one who sees the patient in the preadmission clinic. The non-investigator-anaesthetist who sees the patient in the preadmission clinic, and may not know all the details of the study, is not the appropriate person to obtain informed consent. Is it adequate for him/her to warn the patients regarding the study, as he/she may not be able to answer all the questions raised by the patient? Is it fair to the patient if the consent is obtained on arrival at the clinic, or minutes before surgery, even though the information includes the fact that refusal to participate would not jeopardize the quality of care? When informed consent is obtained through an interpreter, how can one be sure that none of the essential information is lost through the translation?

Clinical reports often simply state that "the study has been approved by the ethics committee and informed consent obtained from patients." However, it is the manner in which the informed consent is obtained in these situations that has not been addressed.

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PCA in burn injuries: the subcutaneous route

To the Editor:

Adequate pain control in burn injuries can be problematic due to wide variations in analgesic requirements.[1] In a retrospective study, 35 hospitalized patients suffering from acute burn injuries were assessed for three days after their injuries. A winged needle was inserted subcutaneously (*sc*) at a site distant from the burns. Morphine was given as an on-demand bolus dose of one milligram (mg) with a lockout time of six minutes. A background infusion of morphine (1 $mg \cdot hr^{-1}$) was used routinely, but was discontinued if morphine requirements decreased below 20 $mg \cdot day^{-1}$.

Every four hours, the respiratory rate, sedation score, pulse rate, and blood pressure were recorded. Each day, an assessment was made of each patient, a database form was filled in, and any complications were noted. The % body surface area burnt was recorded. Pain was assessed daily by the patient using a ten-point visual analogue pain scale. The quality of analgesia was also indirectly assessed by determining the ratio of successful to unsuccessful demands, the proviso being the higher the ratio the better the analgesia (or the less anxious the patient).[2,3]

Vomiting was seen in only one patient. No oversedation or respiratory depression occurred. Localized swelling and induration at the sc infusion site was found in two patients. The sc site was easily resited. A positive relationship between pain scores and body surface area burnt has previously been reported.[4] No such relationship occurred in this study.

However, sc PCA (with morphine) was found to be a safe and effective way of controlling burn pain. There is often a paucity of readily accessible veins in patients with burn injuries. The sc route has the advantage of reducing time taken to maintain a dedicated intravenous line, and is easy to initiate and maintain. To the best of our knowledge, it is the first time that the sc route has been used in this way.

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Hyperkalaemia after warm heart surgery

To the Editor:

We read with interest the case report of severe hyperkalaemia following warm heart surgery.[1] In our experience of over 900 cases of warm heart surgery we have