vulnerable to noise or artifacts situated in the same frequency range as awake EEG and the detection of those artifacts is tricky owing to the variability of the frequency and amplitude of EEGs. High-frequency artifacts may be physiological (coming from sources other than the patient’s brain) and non-physiological (generated by external devices). Examples of the latter case have been reported to falsely increase the BIS. They include but are not limited to: cardiac pacing devices, cardiopulmonary bypass machine, warming blankets, endoscopic shavers, electromagnetic systems, and EMG tracheal tubes. Interference of the patient’s own ECG with the BIS reading has been scarcely documented. Myles and Cairo and Puri and Nakra reported cases where the ECG was detected by the BIS monitoring system and not recognized as artifact in patients with severe brain injury. The BIS values were relatively high (38, 45) whereas they were expected to be extremely low due to low cerebral perfusion and neurological damage. Our patient was on no previous medication known to suppress EEG activity, the awake BIS value was more than 90 and the raw EEG appeared normal. We hypothesize that instead of reading EEG, the BIS monitor read ECG tracings, which reflected long isoelectric periods interrupted rhythmically by the ECG signal with relatively high amplitude, thus mimicking a deep anaesthetic state. We recommend that the raw EEG tracing should be thoroughly investigated whenever BIS values seem clinically dubious.

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Injection pain due to propofol in children and the ethics of placebo

Editor—I was interested in this study of reducing injection pain due to propofol in children, which is a laudable aim. However, I question the ethics of a placebo-controlled trial design in children below age 7 yr in the light of current guidance and the tenets of the Declaration of Helsinki which seeks to protect the best interests of trial subjects. In particular to have one-quarter of the trial subjects exposed to long chain triglyceride (lct)-propofol with no added lidocaine as one of the control arms seems to me to be completely unacceptable. Indeed, this was so in 1992 when we discussed such a study with our ethics committee and agreed that to deny a control group the most efficacious known treatment was unethical and therefore adopted a step-down technique to establish the minimum effective dose of lidocaine for this purpose, namely 0.2 mg kg\(^{-1}\). Thus, the authors of this paper have not only denied analgesia to a control population, but have also exposed trial subjects to more than twice the effective dose of lidocaine, 0.5 mg kg\(^{-1}\). It was also interesting that they had to adjust their power calculations and numbers of study subjects and although they do not say so, I suspect this was because of unacceptable pain experiences of their child patients. I fully appreciate the difficulties of conducting paediatric research, but I was surprised that such a trial design achieved IRB approval and survived the peer review process of a major international journal. I think researchers, editors, reviewers, and ethics committees need to be more aware of modern paediatric ethics standards in order to protect the best interests of both trial subjects and control groups.

Declaration of interest
I am the Editor-in-Chief of the journal Pediatric Anesthesia.
Editor—Dr Morton makes an important point, but I suggest it goes further. Ethics review committees do not have the only word on this matter, nor are they infallible. If an article gets into print, several people who can affect the process should have read and judged the content, and I suggest all should have considered the ethical aspect of the study. Having experienced the discomfort of propofol without lidocaine, I would think twice about consenting to a study such as this. I would be very interested to know if the consent form provided information to the parents about the likelihood of discomfort to the participants. If not, I suspect that the committee has not been vigilant concerning the interests of the subjects.

In addition, the paper must have been read by referees and an editor: each is entitled to object to the ethics of a study, irrespective of the stated approval by an ethics committee. In fact, I would argue that each is obliged to object if they think that the study they are considering is unethical. I read many papers to consider the ethics of animal studies: and always bear in mind the editorial titled ‘The benefit of the doubt goes to the animal’. Here the benefit of the doubt should surely go to the children?

Ethics committees are thought of by many as a nuisance: and they can indeed be wrong. They, as do we all, have a duty to get it right. When they do, they are a valuable and important part of the research process.

Declaration of interest
I am the senior ethics editor for the Journal of Physiology.

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Editor—We appreciate the comments from Dr Morton and Dr Drummond and fully agree with the claim that the best interests of trial subjects must be protected. Dr Morton argues that lidocaine, 0.2 mg kg\(^{-1}\), mixed with propofol provides painless injection in all children and therefore should be the gold standard given to the control group. Not everybody agrees with this statement and several alternative treatments have been tested. Lidocaine, even in larger doses, fails to eliminate injection pain in 24–39% of patients, as discussed in our paper and confirmed in our results. Such controversial data prompted us to refer to the methods of evidence-based medicine, and include a placebo-control group. This is recommended through the Best Pharmaceutical for Children Act, the FDA requests, the European Union Directive 2001/20/EC, or the guidelines of the American Academy of Pediatrics when a reference treatment is not effective enough to be unquestionable. The ethical acceptability of this choice was discussed when the design of the study was developed. A bibliographic research on ethical considerations in paediatric clinical trials over 10 yr was not very helpful: most of the papers were editorial views pointing out aspects of the dilemma but few practical guidelines were available, especially addressing the use of placebo. However, all authors deeply regret that children still remain ‘therapeutic orphans’. In the particular field of injection pain, an uncomfortable but brief and not dangerous condition, it must be considered that the lack of data usually leads to give up preventing injection pain or, more often, to choose inhalation anaesthesia. This choice is not necessarily the best care, as induction of inhalation anaesthesia is not always smooth and may lead to emergence delirium, both uncomfortable conditions that last for much longer than injection pain and occasionally can lead to persistent ‘fear of mask’. In our experience and in this study, few patients experienced major discomfort: seven out of 38 in the control group, two out of 41, two out of 39, and zero out of 39 in treatment groups. None complained about that thereafter. Considering all sides of the problem, the design of our study was accepted and the parents were clearly informed of all aspects of the study.

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NICE and warm

Editor—We read with interest the editorial by Harper and colleagues regarding the recent National Institute of Clinical Excellence (NICE) guidelines on inadvertent perioperative hypothermia. We had been prompted by these guidelines to conduct an audit into current practice at our District General Hospital. A retrospective case note analysis of 57 adult patients revealed poor compliance with the majority of the recommendations. For example, 33% of