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’.3 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.4 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 experience. 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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3 Drummond JC, Todd MM, Saidman LJ. Use of neuromuscular blocking drugs in scientific investigations involving animal subjects: the benefit of the doubt goes to the animal. Anaesthesiology 1996; 85: 697–9
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NICE and warm

Editor—We read with interest the editorial by Harper and colleagues1 regarding the recent National Institute of Clinical Excellence (NICE) guidelines on inadvertent perioperative hypothermia.2 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
our patients had a preoperative tympanic temperature of below 36.0°C, a distribution that has already been noted in a surgical population. A systematic literature review in 2002 found a range of tympanic temperature of 35.4–37.8°C. Is the NICE trigger of 36°C appropriate? Many of our patients are admitted on the day of surgery and data were collected during a relatively warm week in March. We found a postoperative hypothermia rate of 40%, which is double that quoted by Harper and colleagues, but given the 33% preoperative hypothermia rate, is this so bad? Intraoperative warming is indicated for surgery of duration >30 min, that is, in 39 (68%) patients in our audit, but warming was given only in 15 (38%) of those cases. Notably, temperature monitoring was only used in three (8%) of these patients and was of a recommended frequency in only one case. We expected that the performance in the more protocol-based domain of the post-anaesthetic care room (PACU) would be better. However, while nearly all patients (91%) had their temperature measured on admission, the treatment or documentation of hypothermia was minimal. No patient had regular temperature measurement, for 30 (53%) patients no temperature was documented upon return to the ward and five (19%) of those with a documented temperature were hypothermic. We agree with Harper and colleagues these shortcomings will result in additional costs: that of forced-air warmers, disposables, additional thermometers, and longer stays for patients in the PACU. Given the influence of previous NICE guidelines in the purchasing of ultrasound machines and our current shortcomings, we hope to improve care for our patients. Once the audit tool is available, it would be interesting to compare our results with other units in the UK.

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Editor—We thank Drs Williams and Harrison for their interest in our article. As we mentioned, all methods of temperature measurement have significant problems, as the degree of accuracy seems to increase only with their degree of invasiveness. Tympanic temperatures are a particular problem in clinical practice. One of the author’s (C.M.H.) institutions swapped over from temporal artery thermometers to tympanic and found a sudden increase in the incidence of postoperative hypothermia. We then audited the incidence of postoperative hypothermia according to each form of measurement and found that the tympanic thermometer read on average 0.73°C lower than the temporal artery, giving incidences of 9.1% for temporal and 60.3% for tympanic. The temporal artery thermometer has been shown to be reasonably accurate in the clinical situation and has even been used to demonstrate improved outcomes in warmer patients. In fact, this study suggests that outcomes are improved if patients’ temperatures are kept above 36.5°C (reference 16 in the original article).

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Early stages of propofol infusion syndrome in paediatric cardiac surgery: two cases in adolescent girls

Editor—Propofol is widely used for i.v. anaesthesia and sedation in children. The use of propofol for sedation in paediatric intensive care unit (PICU) has been controversial since the report of five unexpected deaths in 1992.1 Propofol infusion syndrome (PRIS) is a rare and often fatal syndrome, originally described in critically ill children undergoing long-term (>48 h) propofol infusion at high-dose regimen (>4 mg kg⁻¹ h⁻¹).

Two girls (12- and 16-yr-old) underwent a second operation for correction of congenital mitral regurgitation on a mitral cleft with normothermic cardiopulmonary bypass (CPB). Anaesthesia was induced and maintained with infusion of propofol, alfentanil or sufentanil, and vecuronium. At the end of surgery, transoesophageal echocardiography showed a balanced contractility of the two ventricles and the lack of residual mitral regurgitation. The children were weaned from CPB with low dose of epinephrine and milrinone and were admitted to the PICU. Sedation and analgesia were obtained using a continuous i.v. infusion of propofol and morphine. The two children progressively developed a metabolic acidosis (Fig. 1). Acidosis persisted, despite administration of sodium bicarbonate. Lactate concentrations increased continuously during short-term propofol infusion and peaked at 9.3 mmol litre⁻¹ for the first child and 14.7 mmol litre⁻¹ for the second one (normal range <1.95 mmol litre⁻¹). No symptoms of myocardial and renal failure, or sepsis or pathological pulmonary findings, were noted. Propofol was infused during 15 and 8 h, respectively, at a dose <3 mg kg⁻¹ h⁻¹ in both girls. The diagnosis of PRIS was