

## From the editors

In this issue,<sup>1</sup> we published a paper on sleep bruxism in children exposed to secondhand smoke (see page 392). After publication, we received a letter (below) raising questions about the ethics of the study. Normally, responses to papers are published electronically as Rapid Responses, because we simply do not have page space for extensive discussions between authors and readers. However, we take research ethics very seriously at

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*Tobacco Control*, and so we are making an exception in this case to share openly with readers our process in responding to the criticism. Because the senior editors felt some of the concerns raised were reasonable, we requested further clarification about the study procedures from the authors (see response below). We also sought an expert opinion from the Department of Bioethics at the US National Institutes of Health (see editorial, below). We invite our readers to review these materials in the interest of furthering reflection on the ethical implications of research on the effects of secondhand smoke, but also on the

research enterprise more generally. While standing behind our decision to publish the paper, we appreciate the thoughtful critiques and responses from our colleagues. We hope you will find the dialogue illuminating.

**Contributors** Ruth Malone, Andrew Hyland, Joaquin Barnoya, Joanna Cohen, Coral Gartner, Sally Haw, Lisa Henriksen.

**Competing interests** None.

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### REFERENCES

1. **Montaldo L**, Montaldo P, Caredda E, *et al*. Association between exposure to secondhand smoke and sleep bruxism in children: a randomised control study. *Tob Control* 2012;21:392–5.

## Meeting our ends by our means: protecting children from SHS in research

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We are concerned by the recent publication of a randomised clinical trial in your journal, in which smoking parents were asked to continue smoking in the presence of their children for 6 months to evaluate if secondhand smoke (SHS) exposure increased the risk of bruxism.<sup>1</sup> It is surprising that after acknowledging that SHS is “...a serious public health threat” with a large impact on children’s health,

ranging from respiratory affections to cardiovascular damage, authors conducted a study in which:

“The smoking members of the families in group 1 were asked not to smoke in the presence of the child for a period of 6 months, while those in group 2 were asked not to change their smoking habits.”

What would have happened if a parent in group 2 had decided to quit smoking during follow-up? Would the investigators have encouraged him/her not to, or to wait until the end of the study? The active involvement of researchers in the decision to expose children to SHS contravenes the Helsinki declaration, since “...the well-being of the individual research subject must take precedence over all other interests”.<sup>2</sup> Preventing family members from stopping smoking and actively seeking children to be exposed to a dangerous pollutant is reckless, as the benefits of knowing if SHS is a risk factor for bruxism cannot overcome

the dangers of exposing children to SHS or the benefits of quitting. A reasonable approach to address the research question posed by the authors would have been to take an observational stance, developing the most effective intervention possible to eliminate SHS exposure at home for all children, closely monitoring bruxism and SHS exposure levels at home over time, and using each child as its own control. The methodological disadvantages associated with this approach would have been clearly balanced by its adherence to the Helsinki declaration.

As we move forward in eliminating SHS exposure, it is imperative that researchers, ethical committees, reviewers and scientific journals remain aware of the ethical implications of research, so our ends are met by our means. Failing to do so undermines participants’ health and the global movement towards SHS elimination. Considering children’s high vulnerability and inherent risks from SHS, we

### What this paper adds

- ▶ The scientific community must remain aware of the ethical implications of second-hand smoke (SHS) exposure research.
- ▶ A careful risk-benefit analysis should guide the ethical considerations of each specific study, but as a general rule experimental studies involving exposure to SHS should be discouraged.

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