Author's response to reviews

Title: Prematurity, asphyxia and congenital malformations underrepresented among hospitalised neonates: an observational study of a tertiary pediatric hospital in Vietnam

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Research article
Prematurity, asphyxia and congenital malformations underrepresented among hospitalised neonates: an observational study of a tertiary pediatric hospital in Vietnam
Alexandra Y Kruse, Ho TT Binh, Cam N Phoung, Lone G Stensballe, Gorm Greisen and Freddy K Pedersen

Clarification of Methods, Ethics

1. Please confirm whether the scientific review board of Ho Chi Minh City Paediatric Hospital Number 1 acted as an ethics committee, in order to approve this study.
   
   **Reply: yes, see below**

2. Since you used data from a Danish hospital for comparative purposes, we would expect to see ethical approval from the Danish ethics committee as well. Could you please confirm whether you received approval from the Danish ethics committee to use these data?

   **Reply: no, not under their jurisdiction**

*Previous wording*

**Ethics**

The study was approved by the scientific review board of PH1 and the Danish Data Protection Agency. Observational studies do not need external approval in Vietnam and were not within the jurisdiction of The Danish National Committee on Health Research Ethics, Subcommittee for Developing Countries.

*Revised wording*

**Ethics**

In Vietnam, the study was approved by the scientific review board of PH, acting as ethics committee, since Vietnam does not have an ethical review committee system yet. Observational studies do not need external approval. In Denmark, the Danish Data Protection Agency approved the study. Observational studies are not within the jurisdiction of The Danish National Committee on Health Research Ethics, Subcommittee for Developing Countries.

A Danish hospital database was used for comparison. This database is part of the standard registration in the hospital. Registry based studies do not need ethical review committee approval and are not dealt with by the committee according to their rules and regulations.

Best regards
Alexandra Kruse