Author's response to reviews

Title: Smart Pumps and Random Safety Audits in a Neonatal Intensive Care Unit: a new challenge for patient safety

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Author's response to reviews: see over
Dear Tom Rowles,

Please find below our comments regarding the suggested corrections to the paper.

Editorial comments:

We note that you state in your manuscript that formal ethical approval was not required for your study. Ordinarily we would expect a study such as yours to require ethical approval. We would therefore ask you to please provide us with more details on why you did not consider this to be necessary on this occasion. In the event that there are local regulations concerning this point, we would ask you to please forward a copy of these onto us.

We have made a new query to the president of the Clinical Research Ethics Committee, Dr. María del Puy Goyache. We reconfirmed that this type of study does not require evaluation by the committee under Spanish law because the objective of the study is a service audit. You could contact her for more documentation if necessary (e-mail maria.puy@salud.madrid.org).

Lines 181-182.