Doctor calls for investigation into possible lack of informed consent in premature baby studies

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In an article in *BMJ*, a senior doctor today calls on several governments around the world to investigate whether parents of premature babies were fully informed of the risks of a study on the health effects of varying oxygen levels, as was not the case in the US.

Dr Sidney Wolfe, founder and senior adviser to the Health Research Group at Public Citizen, says it is surprising that the adequacy of consent forms for nearly identical studies in the UK, Australia, New Zealand, Canada, and other countries with similar regulation of human research, has apparently not yet been examined.

He argues that there may well be "serious problems" with such risk disclosure that must be addressed.

The study, called SUPPORT, was funded by the US National Institutes of Health and took place at many universities across the US between 2005 and 2009. A total of 1,316 extremely premature infants were randomly maintained at either higher (91-95%) or lower (85-89%) ranges of oxygen saturation.

The main aim of the study was to see whether the infants were more likely to die or suffer eye damage and blindness at the different oxygen ranges.

Wolfe says that parents were not adequately informed about the risks or true nature and purpose of the research, but others have staunchly defended this lack of informed consent.

He argues that information on risks and possible outcomes was missing from the consent forms, and that the forms "failed to distinguish the important differences between these clearly experimental procedures for managing the oxygen therapy and the usual individualized standard of care the babies would have received had they not been enrolled in the study."

Worse, he adds, "many of the consent forms falsely stated that because all of the treatments proposed in this study are 'standard of care' there would be no expected increase in risk to the infants."

Others, however, defend the lack of appropriate informed consent. In a recent BMJ editorial, eminent neonatologist Neena Modi implicitly argued that withholding some risk information would "reduce the burden of decision making at difficult and stressful times" and "would also reduce the risk of 'injurious misconception,' where participation is inappropriately rejected because of an exaggerated and disproportionate perception of risk."

But Wolfe suggests that the underlying principle behind these arguments "is that it is necessary, via inadequately informed consent, to blur the line between research and standard of care to facilitate more consent and participation."

This, he concludes, "appears to be exactly what occurred when consent was obtained for the SUPPORT study subjects."

More information: www.bmj.com/cgi/doi/10.1136/bmj.f4198