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Ethics at the beginning of life

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The Ethical Evaluation of Risk in Research Involving Children

A great proportion of medications used for minors have not undergone scientifically acceptable evaluation to assure standards for optimal dose, safety and efficacy. As a result, the majority of children admitted to hospital wards receive medications outside the terms of their product license that apply to indication, age, dose, or route of administration (off-label) or medications that are not specifically licensed for use in children (unlicensed). The major cause of this situation is that children have been excluded from research since they lack the cognitive capacity to give informed consent, and the latter has been seen as a necessary condition for ethically acceptable research that involves risk of harm. As a response to this dilemma, there has been a call to soften the demand for informed consent so as to allow for more research on children. It has been proposed that there is a moral difference between therapeutic and non-therapeutic research. Roughly speaking, non-therapeutic research involves subjects who are not the intended beneficiaries of the eventual results of the research whereas therapeutic research involves subjects who are intended beneficiaries, that is, subjects that might benefit from the results. The idea is that therapeutic research on children involving substantial risks can be morally acceptable whereas non-therapeutic research can only be acceptable if the risks are negligible. Focusing on the issue of what kind of risks it is reasonable to allow people to take and to subject others to, I shall argue that there is therapeutic research that is ethically questionable and non-therapeutic research involving more than negligible risk that is ethically acceptable.