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Human challenge models in Paediatric populations

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BACKGROUND – Human infection (‘challenge’) studies for a variety of pathogens are well accepted models for investigation of vaccine efficacy. While wild-type (wt) organisms were used for paediatric challenge several decades ago, recent paediatric challenge has only been performed with attenuated live vaccines or vaccine candidates. There are complex ethical arguments regarding the inclusion of children in studies where participants are exposed to live infectious agents. This study seeks to systematically review the literature on the involvement of children in challenge studies.

METHODS – Medline, EMBASE and the Cochrane Library were searched without date restriction. Relevant literature was also hand-searched for references. References are being reviewed independently by two researchers for inclusion.

RESULTS – Our search returned a total of 118,341 records for title and abstract screening. From hand-searched literature 74 papers have so far been found.

CONCLUSIONS – Whilst topic such as this involving multiple pathogens and populations without time restriction makes conventional literature searching more difficult, a thorough approach to capture as many examples as possible was felt necessary. There are many different types of human ‘challenge’ from exposure to wt organisms to challenge with live vaccines. This generates different ethical positions, and for clarity, it may be useful to employ different terms to describe challenge with wt organisms and with vaccines. This review will identify a body of literature that will help to define an ethical framework and shape further conversations around human infection models in a paediatric population.