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Letter to the Editor

New pentavalent rotavirus vaccine shows little efficacy against diarrhea

Rotavirus vaccine is recommended as a means of reducing diarrheal morbidity and deaths in developing countries [1]. The original efficacy studies with the presently licensed vaccines were done in the USA and Europe. Efficacy against severe rotavirus infection was around 90% (95% confidence interval (CI): 85.1–94.1) and against all-cause severe gastroenteritis it was about 50% (CI: 39.8–57.8) [2]. Efficacy was less in Africa and Asia. In Africa it was 61% (CI: 44.0–73.2) against severe rotavirus diarrhoea and 30% (CI: 15.0–42.6) against all-cause severe diarrhoea [3].

The journal Vaccine has now published the results of a Phase-III randomized-control-trial of a newly developed pentavalent rotavirus vaccine (BRV-PV). Vaccine efficacy against rotavirus diarrhoea (39.5% efficacy against severe rotavirus gastroenteritis (SRVGE) in the per protocol analysis) is emphasized in the report. However, the incidence of 'all-cause severe gastroenteritis' was not reduced by vaccination – vaccine efficacy was reported as 4.6% (CI: −5.1–13.4) [4].

From the standpoint of the scientific record, additionally highlighting the clinically relevant aspect of their findings - namely efficacy against all-cause diarrheal morbidity, would enable decision makers to make choices about the vaccine, considering costs and benefits.

The same vaccine was studied in Niger. An efficacy of 66.7% against severe rotavirus gastroenteritis was reported in the per protocol population [5]. However severe gastroenteritis due to any etiology was not significantly lower among the vaccinated (difference in rate 1.97 cases per 100 person years confidence interval (CI: −1.28–5.22) [6]. The authors did post-hoc analysis of efficacy against 'very severe diarrhoea' (which they defined as Vesikari score of 15 or more) and reported a difference in rate of 3.08 per 100 person years (CI: 1.79 to 4.36) among the vaccinated. As efficacy against 'very severe diarrhea' has not been studied previously, comparable data for other rotavirus vaccines is not available.

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