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LETTERS

Reply letter in response to "Letter to the editor in response to: Rotavirus vaccine administration patterns in Italy: potential impact on vaccine coverage, compliance and adherence, Martinelli D et al., Human Vaccines & Immunotherapeutics 2020" by Carias and colleagues

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Dear Editor,

We read with interest the Letter from Carias et al.[1] dealing with our paper on the potential impact on vaccine coverage, compliance and adherence exerted by the two different rotavirus vaccines (*RotaTeq* human bovine reassortant vaccine (HBRV) – *Rotarix* human rotavirus vaccine (HRV)) available in Italy.[2]

The authors provided some comments on our review that in principle we certainly appreciated, as they add valuable information for the readers. Nevertheless, we respectfully comment on the arguments of the Letter which may provide a better perspective.

Regarding the age of administration of the first dose, we fully acknowledge the need and value for earliest completion for rotavirus vaccination and agree that 6 weeks of age should represent the target age to start rotavirus vaccination, as recommended by the European Society for Paediatric Infectious Diseases and the European Centre for Disease Prevention and Control and recently underlined by several Italian public health experts.[1]

However, it is a common occurrence that a part of infants is referred for vaccination later than expected. This is observed in the USA as noticed in the Letter by Carias et al. where data from Immunization Information System (IIS) sentinel sites and the Vaccine Safety Datalink (VSD) in the first year following universal rotavirus vaccination recommendation showed that >85% of IIS and >92% of VSD first doses – and not 100% – of HBRV were administered within the recommended upper age limit.[1]

In Italy, a range of 10% to 30% of infants are referred for vaccination older than 12 weeks of age (personal communication) and those babies, according to the HBRV Summary of Product Characteristic[3] (SmPC), would lose the opportunity of being protected from rotavirus disease. Querying the Apulia regional database, we found out that between 2016 and 2020 the mean age at the start of rotavirus vaccination was 11.4 weeks (SD ±2.97), being 25.5% (25,403/99,528) of infants receiving the first rotavirus vaccine dose older than 12 weeks. As underlined in our paper, if parents delay the decision to vaccinate their babies, the HRV approved posology allows to extend the vaccination age to 20 weeks.[4] The extended time frame for the first dose can increase the number of fully protected babies and contribute to an overall higher rotavirus vaccination coverage. The value of the catch-up of late comers for rotavirus vaccination was acknowledged also in some public Regional vaccine tenders in Italy, where a specific allotment for a rotavirus vaccine that could overcome the age limitation of 12 weeks of age was introduced.[5,6]

In our review, it was declared that efficacy and effectiveness data of the studies considered were based on fully and timely completed courses.[2] Furthermore, both vaccine SmPCs state that a complete vaccination series is needed to provide the level and duration of protection against rotavirus gastroenteritis that was observed in the clinical studies.[3,4] Therefore, our considerations on rotavirus vaccination were based on the review of solid evidence and regulatory statements rather than on a unique post-hoc analysis of an incomplete regimen.[7]

Concerning differences in schedule compliance and series completion between the two vaccines, our intent was not to fully draw the picture of current compliance rates in the United States, as done by Carias et al.[1] but rather to show consistencies of the figures reported by Aquilani et al. in their Italian experience with reports coming from other countries with well-established rotavirus universal vaccination, such as USA but also Mexico and Belgium.[2]

Finally, we are not sure about the relevance of the durability of protection reported by Carias et al.[1] as it was not considered in the context of our paper and both vaccines exert a 3-years lasting protection in infants according to their SmPCs.[3,4]

In conclusion, we appreciated the comments on our review which presented an opportunity to further elaborate on its contents. The efficacy and safety of both HBRV and HRV have been demonstrated in large clinical trials, but public health outcomes need to be evaluated in a broad perspective and vaccines posology may introduce impacts that deserve to be considered.

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