Human Papillomavirus (HPV) Vaccination Safety Assessment: The Methods Matter

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To the Editor We write to express our disappointment in the recent publication by Kinoshita et al. (1), in which the authors described the findings obtained for a heterogeneous, opportunistic sample of patients enrolled without defined inclusion criteria. Such methods do not aid in acquiring a better understanding of adverse events following immunisation (AEFI) in Japanese girls given the human papillomavirus (HPV) vaccine.

It is important to remember that AEFI may include events that are causally linked to vaccination or occur purely by chance. An opportunity was wasted here by not using a robust methodological approach to investigate AEFI, including agreed-upon case definitions and epidemiological analyses to assess temporal and biological plausibility. First, as stated in the paper, all girls enrolled in this study were included in the analysis because they ‘complained of several symptoms after HPV vaccination.’ No data were provided regarding vaccinated girls in whom no such events occurred or HPV-unvaccinated girls presenting with similar ‘complaints.’ Instead, the authors included a total of 40 girls who variably had >13 different non-specific symptoms. Furthermore, the range of putative diagnoses applied varied widely, as did the time frame following vaccination. As such, these data do not fulfill the minimum criteria required to suggest causality or even a clear temporal association with HPV vaccination, from either a clinical or epidemiological perspective (2).

Japanese authorities have an opportunity to utilise their epidemiological and clinical resources and benefit from the previous experience of the international community when assessing these concerns. Such investigations should be strengthened by employing well-developed scientific methods for investigating potential vaccine safety signals (3). The international vaccine safety science community are willing to work with Japanese experts to conduct more rigorous and conclusive investigations. By thoroughly utilising data collected in this manner, federal authorities will be able to make fully informed decisions regarding HPV vaccination for Japanese girls and women.

Sadly, the present lack of resolution is expected to result in a high number of preventable cervical cancer cases and other HPV-driven cancers among Japanese women as well as potential damage to the overall Japanese immunisation program.

The authors state that they have no Conflict of Interest (COI).

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References