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LETTER



Cause and consequence of loss in vaccine trust

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Dear Editor,

This letter is written in response to an article by Larson et al entitled "Vaccine confidence plummets in the Philippines following dengue vaccine scare: why it matters to pandemic preparedness". Larson et al are correct in pointing out that vaccine confidence has suffered following the vaccine scare, and that trust needs to be rebuilt before the next pandemic.

However, the authors are mistaken in their inference that public outrage caused the lack of trust. The authors have mixed up cause and effect: the outrage was a result of the loss of trust rather than its cause.

Getting the cause and effect relationship right is critical because it has important implications on how we should go about achieving the goal on which we agree – that is, rebuilding public trust. With a correct reading of causation, it becomes clear that rebuilding public trust will require responsible parties to behave in a trustworthy manner. Here, we point out the specific problems that resulted in outrage and loss of trust, and suggest actions that are necessary to rebuild that trust.

- (1) Multisectoral stakeholders were neither consulted in the program development, sufficiently informed, nor given adequate time to understand the issues before the mass vaccination campaign was launched. Lesson: authorities must ensure public awareness of the issues relevant to major vaccine campaigns.
- (2) There was no public education on the selection process for key advisory bodies that should have addressed conflicts of interest. Lesson: public awareness and input should include and address issues of conflict of interest.
- (3) Sanofi exaggerated the safety and only belatedly declared the dangers of Dengvaxia[™]. Lesson: Industrial vaccine producers should provide information commensurate with realistic benefits and not obscure and hide dangers when troubling data emerges. Hyperbolic claims and hiding dangers are problematic under any circumstance, but especially for massive programs such as this one that involved more than 800,000 children.
- (4) The science was obfuscated, and the conceptual models flawed. The published meta-analysis³ hid data on safety and vaccine dependent enhancement through flawed

- statistical analyses.⁴ The problem was exacerbated by WHO statistical models that insisted on "net benefit", thus ignoring the heterogeneous effects of the vaccine and failing to address the subgroup of children in danger of harm.^{5,6} Lesson: Scientists working on vaccine issues should admit gaps in knowledge. To assure this, they must have financial and intellectual independence from the companies producing the vaccine, thus avoiding the behavior that protected temporarily but disastrously the company to public detriment.
- (5) The state mandate was rushed without sufficient time allowed for a voluntary immunization program. Lesson: Immunization programs should begin as voluntary programs, with fully informed consent that acknowledges both potential benefits and harms.

The authors are correct in their final statement: the global players involved need to examine this experience and consider its handling of risk in times of uncertainty. Indeed so: if public trust is to be restored, these key players must in the future, abide by these 5 principles that, incidentally, Larson herself has previously pointed out. To summarize, they must engage the public, address conflicts of interest, avoid hyperbolic commercial practices, admit gaps in knowledge and delay state mandates.

Finally, the authors fail to declare their conflicts of interest. Dr. Larson has written work and lectures supported by Sanofi, and is associated with organizations with links to that company. Dr. Hartigan-Go was a public health official at the time of the Dengvaxia™ program launch in the Philippines.

Disclosure of potential conflicts of interest

The authors have written papers and have appeared in public, demanding that Sanofi declare the dangers of Dengvaxia [™] for seronegative patients. Dr. Antonio Dans is currently involved in a trial on a flu vaccine produced by Sanofi-Pasteur. This trial is funded by the Wellcome Trust. Over the past 10 years Dr. Halstead has consulted with Sanofi-pasteur, GSK, Takeda and Merck on aspects of dengue vaccine development.

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References

- 1. Larson HJ, Hartigan-Go K, de Figueiredo A. Vaccine confidence plummets in the Philippines following dengue vaccine scare: why it matters to pandemic preparedness. Hum Vaccin Immunother. 2018;1-3. doi:10.1080/21645515.2018.1522468.
- 2. Sanofi updates information on Dengue vaccine. [accessed 2018 Oct 20]. http://mediaroom.sanofi.com/sanofiupdates informationon-dengue-vaccine/.
- 3. Hadinegoro SR, Arredondo-García JL, Capeding MR, Deseda C, Chotpitayasunondh T, Dietze R, Hj Muhammad Ismail HI, Reynales H, Limkittikul K, Rivera-Medina DM, et al. Efficacy and long-term safety of a dengue vaccine in regions of endemic disease. N Engl J Med. 2015;373(13):1195-1206. doi:10.1056/NEJMoa1506223.
- 4. Dans AL, Dans LF, Lansang MAD, Silvestre MAA, Guyatt GH. Review of a licensed dengue vaccine: inappropriate subgroup analyses and selective reporting may cause harm in mass vaccination programs. J Clin Epidemiol. 2017. [First of series]. doi:10.1016/j. jclinepi.2017.11.019.
- 5. Dengue vaccine: WHO position paper July 2016. Weekly Epidemiological Record. 2016 Jul 29;vol. 91, 30. Geneva, World Health Organization, 2016. (pp. 349-364).
- 6. Dengue vaccine: WHO position paper Sept 2018. Weekly Epidemiological Record. 2018 Sep 7;vol. 93, 36. Geneva, World Health Organization, 2018. (pp. 457-476).
- 7. Cooper LZ 1, Larson HJ, Katz SL. Protecting public trust in immunization. Pediatrics. 2008 Jul;122(1):149-153. doi:10.1542/ peds.2008-0987.