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Dengvaxia's Safety: Should Hospitalization Be a Clinical Trial Outcome?

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Abstract
In the Philippines, doctors, parents, and legislators are all still plagued by doubts about the safety and effectiveness of Dengvaxia. There have been ongoing reports of deaths among those who received the vaccine between 2016 and 2017, with an unofficial total of 29 deaths to far, following the mass vaccination of about 850,000 youngsters with Dengvaxia.
The Dengvaxia Clinical Trial was conducted in a number of Asia-Pacific nations, including the Philippines. Capeding et al. released the Dengvaxia Efficacy Trial in 2014, which covered the time after the three doses were finished until the 28th day. The reported 56.5% overall efficacy rate may be deceptive because the efficacy rates for individual serotypes vary greatly. The efficacy against serotype 2, which is regarded as a weakness of Dengvaxia® and is still being studied, was shown to be low (35%) and equivocal in the secondary studies (Sauer J, et al, 2018). Based on the results of 117 dengue cases out of 6848 in the vaccine group and 133 dengue cases out of 3424 in the placebo group, regardless of dengue serotype, the Number Needed to Vaccinate (NNV) is approximately 46. Accordingly, 46 people must receive vaccinations to prevent one case of dengue (Capeding, 2014). On the other hand, the NNV for Dengue type 2 is 322.5, which is nearly twice the number of vaccinations required to prevent one case of Dengue. The NNV for the trivalent influenza vaccine, on the other hand, is 40 for seniors living in the community (Kolber M 2014) and 1031–3050 for childhood influenza, with a 50% effectiveness rate for children aged 6–23 months (Lewis EN, 2007). A systematic evaluation of NNV has revealed no clear threshold for a favorable NNV, despite the fact that NNV has been used to evaluate the cost-effectiveness of a number of vaccines (Hashima, 2014). Disturbingly, however, there were four Capeding deaths reported in the vaccine group, indicating a likelihood of one fatality out of 1712 as opposed to none in the placebo group. There was a substantial temporal correlation between the delivery of Dengvaxia and one of the deaths, which was caused by acute disseminated encephalomyelitis and happened seven days after the vaccine was administered. The remaining fatalities were determined to be unrelated to Dengvaxia and were caused by injuries. I believe it is premature to rule out a connection between the vaccine and these deaths. Many years ago, benzodiazepine use was the real cause of car crashes and falls, particularly among the elderly (Pariente, 2008), which may not seem likely at first.

Unfortunately, more questions and concerns regarding the safety and effectiveness of the vaccine were raised by the Efficacy and Long Term Safety Study of Dengvaxia® in endemic locations, which involved participants who received the three doses of Dengvaxia up to the 25th month after vaccination.

According to the findings of CDY 14, the Dengvaxia Trial in the Asia Pacific Region, the vaccine group saw a higher rate of hospitalization and severe dengue, particularly among individuals who were seronegative before receiving Dengvaxia (Hadinegoro 2015).
Only 13 out of 3887 (33.44%) hospitalizations for Dengue were reported in the placebo group, compared to 27 out

of 6778 (39.83%) in the vaccine group. For the entire cohort, we determined a NNV of (-) 6896; the negative figure changes the NNV to the Number Needed to Harm (NNH), indicating that one hospitalization will occur out of 6896 children who received the Dengvaxia vaccine. Those in the age categories under 9 and over 9 years old continued to have this negative NNV(-502) near the third year after vaccination. A high NNH is preferable to NNT, which is advantageous if it has a low value.

Why is hospitalization used to gauge results? Ironically, vaccine studies are intended to prevent diseases rather than treat them; they target healthy people. Hospitalizations, such as deaths, disabilities, and congenital abnormalities, are regarded as serious adverse events and serve as a warning regarding the safety of the product under study if drug regulations have not changed.

Sanofi may have anticipated the increased likelihood of a second dengue episode in endemic environments since Dengvaxia® does not provide cross-protection for other strains of dengue. According to Sacket's suggested mechanism, the Antibody Dependent Enhancement phenomenon, which was initially reported following the Dengue outbreak in Thailand and the Philippines, the second episode is probably going to be more severe and naturally lethal. The greatest Dengue vaccine, according to clinical research, is one that not only shields the child against the initial illness but also lessens the severity of a subsequent episode, something that Dengvaxia sadly could not accomplish. Even though dengue is endemic in the Philippines, children 9 years of age and older had relatively little protection with Dengvaxia overall, a time when seropositivity should be higher in a dengue-endemic nation.

Was it worthwhile to invest 3.5 billion dollars on the dengue vaccine, which is the same amount as the nation's total dengue control program? According to the WHO Fact Sheet, which was revised in 2017, dengue has killed 25,000 people worldwide, or 2.5% of the 500,000 instances of severe dengue that have been reported. These figures pale in comparison to the 500,000 influenza-related deaths that occur globally. Furthermore, 75% of dengue cases are subclinical or resolve on their own without causing disastrous consequences, whereas only 25% of cases are symptomatic. Those with symptomatic dengue infections also had a low case fatality rate (0.44%).

Is the vaccination secure? Even older vaccines, like MMR, have been linked to some serious side effects. For instance, the rate of likely or ambiguous adverse events of MMR was estimated to be 5.3 /100,000 after decades of use by 1.8 million persons and 3 million doses (Patja 2012). There was only one recorded death from MMR-related febrile seizures. On the other hand, by the third year after vaccination, Dengvaxia had already caused four deaths and increased hospitalization risk in a group of just 6851 exposed.
The number of deaths and autopsy results, which the Public Attorney's Office forensic expert described as rapid and marked by massive bleeding and enlargement of nearly all internal organs, are warning signs to not only provide intervention but also to monitor this cohort of Dengvaxia vaccinees in order to identify any future adverse events. Dengvaxia does not currently exist in the Philippines or possibly anywhere else where the course of dengue infection is comparable to that of the nation.
It seems to reason that if we can establish a program that can identify the cause of a child's fever at the community level, separate out Dengue cases for verification, and provide prompt, appropriate, and aggressive treatment, a considerable number of deaths will be prevented. In the Philippines, children who contract dengue die as a result of delayed diagnosis and, consequently, delayed or nonexistent treatment. The Philippines is home to all dengue serotypes and a large population of vector mosquitoes. In my opinion, there is no benefit to the vaccine over consistent and dependable vector control in conjunction with early detection of Dengue illnesses, especially considering the number of deaths that were reported following the mass vaccination.
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