'Indian' Vi Conjugate Typhoid Vaccine: Misleading Claims

I refer to the article "Vi conjugate Typhoid Vaccine" written by Garg SP(1) on behalf of the manufacturer of Peda Typh^{TM} in response to my previous article on the same subject(2). The author states that "*this novel vaccine has been found to be safe and effective in inducing very high levels of immune response (>90%) in infants, young children and adults*", and goes further to claim that "*this new vaccine can be used to vaccinate and protect patients after clinical recovery and thus prevent disease carriers and relapses*"(1). Both these statements are misleading as for any typhoid vaccine, immuogenicity is not equal to efficacy, and serological correlates of protection for typhoid vaccines are not known. If the correlates were well established (as quoted by the author citing an old 1935 reference) why were the efficacy trials conducted for all the typhoid vaccines subsequently before they were marketed. Such field efficacy trials were also conducted for the experimental Vi conjugate vaccine (Vi-rEPA) by Dr. Robbins and are underway for other Vi conjugate vaccines in India. No such efficacy trial is available for Peda Typh^{TM} anywhere in India or world. Claims that the vaccine will work in preventing carrier stage, and that it is expected to result in eradication of typhoid fever, are tall and misleading as no such data exists for any of the typhoid vaccine.

Author further states that "*over the years, the protective immunity conferred by Vi antigen has been well established and adopted by the WHO*" and quote a 1994 WHO Technical Report Series for the same(1). Again, this is misleading as the said reference does not talk of any such correlate and the said document anyway applies to Vi polysaccharide (unconjugated) vaccine and not Vi conjugate vaccine (which is a totally different vaccine). As the current Indian vaccine Peda Typh^{TM} is different from the experimental Vi conjugate vaccine (Vi-rEPA) of Dr Robbin's, the field efficacy data of later can not be extrapolated or bridged to former.

Lastly, when I suggested conducting a proper field efficacy trial enrolling enough number of subjects, it meant a field efficacy trial in a randomized double blind placebo controlled fashion, and not in a haphazard manner. The onus of conducting a scientific and authentic field efficacy trial lies on the manufacturer (that too before marketing), and not doctors, the end users. I reiterate that there is not enough evidence in using the so called first Indian Vi conjugate vaccine.

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REFERENCES

1. Garg SP. Vi conjugate typhoid vaccine. Indian Pediatr 2009; 46: 736-737.
2. Shah N. Indian conjugate typhoid vaccine: Do we have enough evidence. Indian Pediatr 2009; 46: 181-182.

Editorial Note: The present communication is the last in the series of letters on the Vi conjugte typhoid vaccine, which started from Februry 2009 issue of *Indian Pediatrics.*