

practitioners. There is a mention of demerits of the conjugate Vi vaccine marketed in India in the IAP Immunization Guidebook 2008(1).

Typically any new vaccine (or for that matter any new drug) has to undergo phase 1 (early safety and dosing study), phase 2 (safety, dosing and immunogenicity study) and phase 3 (field efficacy and further safety study) trials before being licensed(2). In case one brand of the concerned vaccine with satisfactory efficacy data is already licensed, and serological correlates of protection for the vaccine are clearly known, a new brand need not do efficacy trials and can be licensed provided it shows non-inferiority (not more than 10% lower than for the lower CI) in comparative immunogenicity trials. Such non-inferiority results will assume and extrapolate similar efficacy for the new brand as compared to the existing vaccine (what is called bridging studies)(3). The new brand has to show non-inferiority over the existing brand in seroconversion (not more than 10% lower for the lower confidence interval compared to the existing brand) and GMCs (not less than 0.5 times as compared to the existing brand).

However if the serological correlates of protection are not known for a vaccine, one has no choice but to conduct field efficacy trials to prove non-inferiority compared with the existing licensed vaccine, example of such vaccines being pertussis vaccines for which huge and expensive field efficacy trials were conducted by most manufacturers(4); and typhoid vaccines. Serological correlates of protection are not known for the existing unconjugated Vi vaccine, oral Ty21a vaccine or the old whole cell killed typhoid vaccines. This is the reason why for each of these vaccines field efficacy trials have been conducted and reported(5). This is the reason why other Indian manufacturers are busy conducting field efficacy trails with their own candidate conjugate Vi vaccine(2).

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## REFERENCES

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## Alleviation of Pain Associated with Immunization Injections

I often come across prescriptions recommending hot fomentation for relief of post vaccination pain and tenderness over the injection site. Many pediatricians prescribe ice packs/cold compress; others prescribe Thrombophob ointment application, besides paracetamol. What is the stand of IAP on this vital issue?

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## Reply

Comfort measures, such as distraction (e.g., playing music or pretending to blow away the pain),