patients and those on immuno-suppression. There are four known genotypes of HEV. The most recent candidate vaccines have been two recombinant HEV vaccines. The first of these vaccines was based on a 56-kDa baculovirus-expressed ORF2 protein produced in Spodoptera frugiperda cells, developed at the National Institutes of Health, later licensed to GlaxoSmithKline. A phase II clinical trial was conducted in 1,794 young male military recruits in Nepal who received three doses 20 μg of the alum-adjuvanted vaccine or placebo. Vaccinees were followed up to 2.2 years. The vaccine showed a 95% efficacy after the third dose. This vaccine study was limited by the fact that it was tested on almost exclusively young males, it did not measure the HEV infection rate and that antibody titers declined by the end of the study. The second vaccine was developed by researchers at Xiamen University in China, using a new recombinant HEV protein expressed in Escherichia coli. This vaccine, HEV 239 (Hecolin), was tested in a randomized, controlled trial involving 112,604 healthy participants aged between 16-65 years in Jiangsu Province, where HEV genotypes 3 and 4 are more prevalent. In those who received all three doses, 87% maintained antibodies and remained protected against HEV for up to 4.5 years. Its efficacy against HEV genotypes 1 and 2, in pregnant women and those younger than 16 years and older than 65 years are yet to be assessed. The vaccine is licensed for use in China. Though not yet prequalified by the WHO, the WHO is ready to assist national health authorities and regulators in a rapid assessment of this vaccine. Today, the real challenge will be to get an HEV vaccine to those who need it the most, at an affordable price.

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Safety, immune lot-to-lot consistency and non-inferiority of a fully liquid pentavalent DTwP-HepB-Hib vaccine: Results from Phase III licensure study of Shan5™

A. Sil*, B.N. Patnaik, V.J. Midde
Shantha Biotechnics Private Ltd (A Sanofi Company), Hyderabad, India

Background: Pentavalent combination vaccines perform a key role in increasing vaccine coverage rate; and provide an efficient and reliable method of implementing WHO recommendations for controlling diphtheria, tetanus, pertussis, hepatitis B and Hib infections on a worldwide basis.

Methods & Materials: Study design: A phase III, multi-center, randomized, single blinded study of a fully liquid pentavalent DTwP-HepB-Hib investigational vaccine (Shan5™) was conducted across India in healthy toddlers and infants. Cohort 1 consisted of 15 toddlers aged 15–18 months, administered with a single booster dose; Cohort 2 consisted of 1085 infants aged 6–8 weeks, administered 3 doses at 6–8, 10–12 and 14-16 weeks of age.

Objectives: Subjects in Cohort 1 were evaluated for safety and immunogenicity. Immunogenicity and safety were evaluated in Cohort 2 subjects vaccinated with a three-dose primary immunization of either the investigational vaccine or a locally licensed comparator vaccine (Pentavac™ SD). Immune consistency analysis among three lots of the investigational vaccine, and immune non-inferiority analysis of pooled (three lots) data of investigational vaccine versus comparator vaccine were also evaluated in cohort 2.

Results: The vaccines demonstrated comparable safety and immune responses in cohort 1. In cohort 2, immune non-inferiority against the comparator vaccine (primary endpoint) was demonstrated for all five antigens and safety results (secondary endpoint) were comparable between vaccine groups. Equivalent immune consistency among three lots was observed for all antigens except whole cell pertussis antigens, where a marginal variation was observed. The variation was linked to the low power of the test and concluded to be clinically insignificant.

Conclusion: The investigational, fully-liquid, whole-cell pertussis (wp) containing pentavalent vaccine has a good safety profile and immunologically non-inferior to the licensed comparator vaccine. This study was the basis for licensure in India and also WHO-prequalification for international use.

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Correlates of county-level non-viral sexually transmitted infection hot spots in the US

B. Chang1*, W. Pearson2, K. Owusu-Edeusi Jr.2
1 Icahn School of Medicine at Mount Sinai, New York City, USA
2 Centers for Disease Control and Prevention, Atlanta, USA

Background: Studies on county-level hot spots of sexually transmitted infections (STIs) in the entire U.S. and their association with socio-economic factors are lacking. In this study, we used a combination of hot spot analysis (HSA) and spatial regression to examine the county-level correlates of the most commonly reported curable sexually transmitted infections (STIs) in the U.S.

Methods & Materials: We obtained reported county-level total case rates of chlamydia, gonorrhea, and primary and secondary (P&S) syphilis in all counties in the 48 contiguous states using the National Notifiable Disease Surveillance System (NNDSS). We computed temporally-smoothed rates using 2008–2012 data. Covariates were obtained from county-level multiyear (2008-2012) American Community Surveys (ACS) from the US census. We conducted HSA (applying the false discovery rate (FDR) correction) to identify hot spot counties for all three STIs. Hot spots were defined as counties or clusters of counties with rates above the global mean (p < 0.05). We used logistic spatial regression with the spatial error model (SEM) to determine the association between hot spots and the covariates and variance inflation factor (VIF < 10) analysis to reduce the effect of multicollinearity on the coefficients.

Results: HSA indicated that > 80% of hot spots for each STI were in the South. Spatial regression results indicated that, compared to White non-Hispanics, a 1% increase in the percentage Black non-Hispanic was associated with a 3.3% (p < 0.01; chlamydia), 3.8% (p < 0.01; gonorrhea) and 2.5% (p < 0.01; P&S syphilis) increase in the odds of being a hot spot county (Table 1). Compared to the other regions (West, Midwest and Northeast), counties in the South were