

Background Morbidity in HIV Vaccine Trial Participants from Various Geographic Regions As Assessed By Unsolicited Adverse Events

Abstract:

Recently, more clinical trials are being conducted in Africa and Asia, therefore, background morbidity in the respective populations is of interest. Between 2000 and 2007, the International AIDS Vaccine Initiative sponsored 19 Phase 1 or 2A preventive HIV vaccine trials in the US, Europe, Sub-Saharan Africa and India, enrolling 900 healthy HIV-1 uninfected volunteers. OBJECTIVE: To assess background morbidity as reflected by unsolicited adverse events (AEs), unrelated to study vaccine, reported in clinical trials from four continents. METHODS: All but three clinical trials were double-blind, randomized, and placebo-controlled. Study procedures and data collection methods were standardized. The frequency and severity of AEs reported during the first year of the trials were analyzed. To avoid confounding by vaccine-related events, solicited reactogenicity and other AEs occurring within 28 d after any vaccination were excluded. RESULTS: In total, 2134 AEs were reported by 76% of all participants; 73% of all events were mild. The rate of AEs did not differ between placebo and vaccine recipients. Overall, the percentage of participants with any AE was higher in Africa (83%) compared with Europe (71%), US (74%) and India (65%), while the percentage of participants with AEs of moderate or greater severity was similar in all regions except India. In all regions, the most frequently reported AEs were infectious diseases, followed by gastrointestinal disorders. CONCLUSIONS: Despite some regional differences, in these healthy participants selected for low risk of HIV infection, background morbidity posed no obstacle to clinical trial conduct and interpretation. Data from controlled clinical trials of preventive interventions can offer valuable insights into the health of the eligible population.