

Fourth Annual Conference

ABSTRACTS OF SUBMITTED POSTER PRESENTATIONS

P1 POPULATION-BASED INCIDENCE RATES OF INVASIVE PNEUMOCOCCAL INFECTION IN CHILDREN IN 7 CENTERS ACROSS CANADA, 1994-1998. G Bjornson, D Scheifele, S Halperin for Members of the CPS/LCDC Immunization Monitoring Program, Active (IMPACT), Ottawa, ON, Canada.

Objective: To determine the incidence rate of invasive pneumococcal infections in children ≤ 12 years of age in 7 major urban centers across Canada. This information will help program planners determine the case for the new 7-valent conjugate pneumococcal vaccine.

Methods: Active surveillance for invasive pneumococcal infections was conducted at the children's hospitals in Vancouver, Halifax, Quebec City, Ottawa, Calgary, Edmonton and Winnipeg since 1993 as part of IMPACT. Cases were defined by isolation of *Streptococcus pneumoniae* from blood or other normally sterile fluid. Cases ≤ 12 years of age from 1994 to 1998 were reviewed to identify residents of the 7 immediate areas. All other pediatric wards and any private biomedical laboratories in the areas were asked to search their records for eligible cases. Duplicates were removed. Rates were compared using the chi-square test.

Results: A total of 653 resident cases were identified during the 5 year period. The highest incidence rates were in children ≤ 23 months with a group mean of 81.5 cases/100,000/year (range 49.2-112.2). The peak rate occurred in children 6-17 months with a group mean of 109.0 cases/100,000/year (range 56.5-161.2). The average rate of meningitis cases over the 5 years in 0-23 month was 8.9/100,000/year (range 3.1-12.0). None of the rate differences between centers were statistically significant.

Conclusions: Invasive pneumococcal infections are relatively common in Canadian children regardless of area of residence. The present data will provide a suitable baseline for measurement of the impact of new vaccination programs utilizing the 7-valent conjugate vaccine.

P2 ESTIMATES OF ROTAVIRUS ASSOCIATED DIARRHEA (RAD) HOSPITALIZATIONS IN QUEBEC CHILDREN FROM 1985 TO 1998

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Introduction: In order to assess the benefits that might accrue in Quebec from a universal immunization program against rotavirus, we estimated the number of hospitalizations associated with rotavirus from April 1985 to March 1998.

Methods: Information on all hospitalizations for diarrhea in children 1 to 59 months old for the study period was obtained from the provincial database. We applied three different methods to estimate the number of hospitalizations associated with rotavirus during the study period. First, we calculated the difference between all winter and summer hospitalizations. Second we multiplied all diarrhea hospitalizations by a ratio 0.37 observed in Toronto between the number of laboratory confirmed RAD and all diarrhea hospitalizations. Third, we applied monthly and age weighted ratios between RAD and all diarrheas hospitalizations observed in Washington over a 7 year period.

Results: There were 63 827 hospitalizations recorded for diarrhea on a cumulative denominator of 5.8 million persons-year. Annual outbreaks peaked between February and May. From year to year, we observed an alternance between high and low peaks throughout the period. Crude incidence rates decreased from 2113 per 10⁵ for 1-11 months old children to 414 per 10⁵ for the 48-59 months old. Mean hospital stay varied from 6.0 days in 1-11 months children to 2.8 in 48-59 months. The three methods produced very similar results with an estimated mean annual number of 1500 RAD hospitalizations in children for an incidence of 320 per 10⁵ RAD hospitalizations.

Conclusion: Rotavirus explains nearly 40% of hospitalizations in children. The alternance from year to year of high and low peak epidemics was an unexpected finding.

P3

P4 Social Harms Evaluation in the First Phase III HIV Vaccine Efficacy Trial

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Objectives: To describe procedures and conventions used in evaluating social harms from The VaxGen Study. To describe current social harms findings from the ongoing trial.

Methods: This ongoing study is the first phase III evaluation of a candidate vaccine to prevent HIV infection (AIDSVAX® B/B). The randomized, double blind, placebo-controlled trial is being conducted in 5418 men who have sex with men and heterosexual women at high risk for HIV infection across 61 sites in the U.S., Canada, and Europe. Data on social impact from trial participation is collected at 6-month intervals. Event-driven social harms data are also collected and categorized based on volunteers' perceptions of harm. Sites provide detailed action plans for any unresolved events and follow-up reports every 6 months through resolution. Data review is conducted on an ongoing basis to assess for potential study-wide trends.

Results: More than 60% of volunteers report beneficial impact from participating and only a small proportion (7%) report any negative social impact. The majority of negative impact is related to disturbances in personal relationships (5%), followed by involuntary disclosure (1%). Other types of negative impact comprise less than 1% of total reported events. A decline in all categories of negative impact is seen over time. The incidence of social harm reports has been low (2% of all volunteers) to date, with the majority of events being attributed to personal relationships (60%) and classified by volunteers as having minimal or moderate impact on their lives. Social harms related to employment and life insurance are reported at lower frequency. Most events are resolved at the time of initial reporting, whereas a minority resolves in 3-6 months.

Conclusions: The overall incidence of negative impact and social harm is low. The majority of negative impact and social harm is due to volunteers' disclosure of their study participation, which may result in negative judgment, stigmatization, or in some cases, discrimination. In developing HIV preventative vaccines, it is important that sponsors and site staff work to address negative social impact or harms that may be experienced by volunteers and provide advocacy for the fair and ethical treatment of participants.

WITHDRAWN