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Title: Risk factors that determine time to first RSV hospitalization in CARESS: The Canadian registry of palivizumab (2005-2011)

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Body: Objective: Evaluate risk factors that determine time to first RSV hospitalization in children at high-risk of RSV infection who received prophylaxis. Design/Methods: A prospective, observational, registry of infants who received 1 dose of palivizumab during the 2005-2011 RSV seasons across 30 sites. Neonatal and demographic data were collected from the parent/caregiver at enrollment. Data related to respiratory infection events were collected monthly. Results: 10,452 infants were enrolled; average age 5.5±6.0 months. Infants were typically male (56.4%), Caucasian (71.3%), average gestational age (GA) 32.3±5.6 completed weeks. 7006 (67%) infants received palivizumab for prematurity (35 weeks GA) only, 836 (8 %) had chronic lung disease, 1048 (10%) had congenital heart disease and 1562 (15%) had underlying medical disorders (e.g. CNS disorders, airway anomalies and cystic fibrosis). Hospitalization rates for respiratory and RSV-related illness were 6.4% and 1.6%, respectively. Risk factors that predicted RSV hospitalization included: having siblings (HR=2.16, df=1, p=0.001), >5 people in household (HR=2.02, df=1, p<0.0005) and smoking exposure (HR=1.80, df=1, p=0.002). Risk of shorter time to first hospitalization increased with the number of risk factors from 1 (HR=3.42) to 3 risk factors (HR=10.40). Conclusions: Time to first RSV hospitalization after the first palivizumab dose are similar to those reported in the literature, with a natural history of RSV. The effect of multiple risk factors pose a cumulative increased risk for RSV hospitalization, similar to the Canadian and European risk scoring models for 33-35 weeks' GA infants.