European Respiratory Society
Annual Congress 2013

Abstract Number: 3530
Publication Number: P3612

Abstract Group: 7.3. Cystic Fibrosis
Keyword 1: Vaccination **Keyword 2:** Bronchiolitis **Keyword 3:** Infants

Title: RSV hospitalization in cystic fibrosis in the Canadian registry of palivizumab (CARESS) following prophylaxis (2005-2012)

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Body: Objective: The Canadian Registry of Synagis (CARESS) tracks palivizumab utilization and respiratory syncytial virus (RSV) hospitalizations in high-risk infants. This study compares respiratory illness (RI) and RSV positive hospitalization (RSVH) rates in CF infants versus: 1) those with other underlying medical disorders (MD) and 2) those meeting standard indications for RSV prophylaxis (SD). Methods: A prospective, observational registry of infants from 32 sites who received >1 dose of palivizumab during the 2005-2012 RSV seasons. Palivizumab utilization and RI outcomes were collected monthly over each individual season.Results: 13,310 infants were enrolled (CF: 234, 1.8%; MD: 1863, 14.0%; SD: 11213, 84.2%). There were significant differences ($p<0.05$) between the three groups in gestational and enrolment ages, weight at birth and enrolment and proportions of: males, Caucasians, siblings, multiple births, daycare attendance, exposure to smoking, household crowding, immediate family history of atopy, and complexity of neonatal course. Infants with CF had a lower RI hospitalization rate than the MD (3.8% vs. 11.2%, $p<0.0005$) but not the SD group (5.9%, $p=0.257$). For RSVH rate, CF infants were not significantly different from the MD (0.55% vs. 2.21%, $p=0.232$) or SD (1.47%, $p=0.999$) groups. In the Cox proportional analysis, infants with CF were not at a higher risk of RSVH than MD (hazard ratio [HR]=0.763, 95%CI 0.512-1.136, $p=0.183$) or SI (HR=0.353, 95%CI 0.05-2.52, $p=0.299$).Conclusions: This is the largest report of CF infants who have received palivizumab world-wide. Despite RI rate differences, RSVH rates appear similar to those in MD and SD.