

mechanical ventilation. Only 1 patient admitted to ICU was previously healthy. Antiviral therapy was administered in 103 patients (51.5%) after a median of 2 days from onset of symptoms. Secondary bacterial infection was identified in 8/200 (4%). The median length of hospital stay was 4 days (range 1-72). Death occurred in 2 patients (1%), who both had severe prior medical conditions.

**Conclusion:** Pandemic H1N1 influenza rarely requires hospitalization and, in hospitalized children, it mainly appears to cause a mild disease. The presence of pre-existing conditions is the most significant risk factor for severe disease.

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### POPULATION PHARMACOKINETICS ANALYSIS OF MOTAVIZUMAB IN CHILDREN AT RISK FOR RESPIRATORY SYNCYTIAL VIRUS INFECTION

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**Aims:** To develop a population pharmacokinetics (PK) model and evaluate the impact of demographic covariates on PK of motavizumab in young children.

**Methods:** Motavizumab serum concentrations from 6 pediatric (n=4316) studies and an adult study (n=30) were modeled simultaneously using nonlinear mixed-effects modeling. Children  $\leq 24$  months received up to 5 monthly doses of motavizumab 3 or 15 mg/kg. The structural PK model with different random effect assignments was evaluated first followed by assessment of effect of chronologic age (CA), gestational age (GA), body weight (BW), sex, race, and presence of CLD on motavizumab clearance (CL) and volume of distribution (V<sub>2</sub>) using NONMEM.

**Results:** Motavizumab serum PK best fit a two-compartment model; CL and V<sub>2</sub> increased with BW. CL and V<sub>2</sub> were related to the sum of GA and CA and were described using an asymptotic-exponential model. Covariate analysis identified 7% lower motavizumab serum CL in infants without CLD compared with infants with CLD. V<sub>2</sub> was 23% lower in Hispanic infants compared with other races. After accounting for demographic covariates, there was 25% inter-individual variability in CL and 23% residual variability in motavizumab concentrations.

**Conclusions:** Population PK analysis of motavizumab concentrations demonstrated increased clearance with CA and BW. Motavizumab serum concentrations were similar across a range of GA, CA and BW confirming appropriateness of BW-based dosing. Given the inter-individual variability in motavizumab concentrations, the marginally lower clearance in patients without CLD and slightly lower volume of distribution in Hispanic patients are not expected to be clinically significant.

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### OCCURRENCE OF BACTERIAL INFECTIONS WITH RESPIRATORY DISEASES AT CHILDREN AGE

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**Introduction:** The most common factors for the occurrence of respiratory infections at children age are the viral infections in 79% of the occasions, bacterial infections occur in 21% of the occasions. Bacterial infections appear very rarely at routine microbiological inspection of throat and nose and most frequently the saliva remains sterile.

**Aim:** To authorize the use of antibiotics in antitoxinograms with respiratory infections of established bacterial isolate.

**Method and Results:** The data is compiled from medical records statistically observed in the period from 2002-2006. Microbiology had served: mouth and nose saliva, less frequently tracheal aspirates. 3.400 children have been treated, out of which 870 children have positive bacteriologic nose saliva. Of those 870 children: 470 have *Moraxella catharalis*; 150 have *Streptococcus pneumoniae*; 117 have *Haemophilus influenzae*; 88 have *Haemophilus* species; 45 have A group of *Streptococcus pyogenes* e. t. c. Positive throat saliva appears in 77 children, the most common bacteria are: A group of *Streptococcus pyogenes* appears with 42 children; *Haemophilus influenzae* appears with 7 children; *Haemophilus* species with 5 children; *Streptococcus pneumoniae* appears with 23 children. Positive bacteriologic finding of tracheal aspirate appears with 15 children and the most frequent bacteria are *Streptococcus pneumoniae*; *Haemophilus influenzae*; *Moraxella catharalis*; and *Klebsiella*.