illness (RIH rate: 7.03%) of which 196 tested RSV-positive (RSVH rate: 1.76%). All RIHs were probably related to palivizumab, and 62 SAEs were documented in 52 infants. Fourteen events in 6 patients out of 62 SAES were hyper-sensitivity reactions (mild: 11; moderate: 3). These were deemed possibly (n=5) or probably not related (n=5), and unclassifiable (n=4). CONCLUSIONS: Using an active surveil-

lance system, a very small proportion of infants in the CARESS registry experienced SAEs that had a clear relationship with palivizumab and these events appear to be idiosyncratic. In routine practice, palivizumab appears to be a safe and well-

tolerated antibody for RSV infection prophylaxis in high-risk children.

HIGH DOSE VANCOMYCIN LOADING VERSUS LOW DOSE IS ASSOCIATED WITH DECREASED NEPHROTOXICITY IN EMERGENCY DEPARTMENT SEPSIS PATIENTS

METHODS: This was a retrospective cohort study performed in three EDs. An electronic health record (EHR)-based clinical decision support tool provided guidance at the point of order for IV vancomycin compliant with recommendations. Inclusion criteria: age > 18 years, IV vancomycin in order, and hospital admission. Exclusion criteria: no documented, weight, hemodialysis-dependent, or < 2 creatinine (Cr) values. The primary outcome was incidence of nephrotoxicity within 5 days defined as at least 2 serial Cr higher than the initial measurement by at least 0.5 mg/dL or 50%. The secondary outcome was acute kidney injury (AKI) within 5 days, defined as any single increase in Cr by > 0.5mg/dL or 50%.

RESULTS: A total of 1592 consecutive patients prescribed IV vancomycin over 6 months. Of these, 1330 patients met study criteria for the primary outcome (83%) and 1461 patients met criteria for the secondary outcome. Nephrotoxicity occurred in 8% of patients. High dose vancomycin was associated with a lower rate of nephrotoxicity (6% vs 11%, p<0.05) and a lower rate of AKI (8% vs 13%, p<0.05). CONCLUSIONS: Initial dosing of vancomycin versus 30mg/kg according to guidelines was associated with a decreased rate of nephrotoxicity compared with low doses. Future analyses should distinguish between the occurrence of nephrotoxicity due to disease progression in severe sepsis versus vancomycin exposure.

SAFETY PROFILE OF FLUOROQUINOLONES: ANALYSIS OF ADVERSE DRUG REACTIONS IN RELATION TO CONSUMPTION DATA USING PHARMAVIGILANCE DATABASE IN HEBEI, CHINA

OBJECTIVES: The aim of this study was to reassess the safety profile of fluoroqui-

nolones using the database of adverse drug reactions (ADR) Spontaneous report system systems from the China database of Fluoroquinolones. Emphasis was also given to the risk factors associated with drug reactions.

METHODS: The SHRDR database related to fluorquinolones were retrieved from Center for Drug Monitoring and Evaluation (CDME) of Hebei. Reports were classified by System Organ Classes with use of MedDRA. ADRs were evaluated by the spontaneous reporting rate (standardized to the population size) for each drug. ADRs were classified as non-serious or serious. Serious ADRs were defined as leading to death, life-threatening, hospitalization, or any other sequelae that could result in a significant health risk.

RESULTS: A total of 2131 patients were included in the analysis. The most common ADRs associated with fluoroquinolones were related to the musculoskeletal system and the connective tissue, nervous system, respiratory system, skin and subcutaneous tissue, gastrointestinal, general disorders and administration site reactions. Compared with other classes of antibiotics, adverse reactions from fluoroquinolones were more common in patients receiving a higher daily dose.

CONCLUSIONS: The safety profile of fluoroquinolones was reassuring in China. However, clinicians should be aware of the risk of severe ADRs in high-risk patients and avoid their use in these individuals.