Chinese rotavirus vaccines: what's around the corner

Rotavirus (RV) is the leading cause of severe gastroenteritis in children worldwide both industrialized and developing countries. In China. hospital-based studies indicated that RV-associated hospitalizations accounted for 32%–50% of all hospitalizations, our population-based surveillance measured an occurrence of ~10/100person/year in children less than 5 years of age. Shortly after the licensure of the first rotavirus vaccine – RotaShield in August 1998, the Lanzhou lamb rotavirus vaccine (LLR, is characterized as G10P[12]), originally isolated from a lamb with diarrhea was licensed in China since 2000. As of 2016, a total of >70 million doses of LLR had been distributed to children countrywide. However, the efficacy of LLR has not been recognized internationally as it has not been confirmed by a properly designed pre-licensure clinical trial. Effectiveness identified by the case-control design nested in our population-based surveillance was 35.0% (95% CI: 13.0%–52.0%), with a highest protection of 52.0% (95% CI: 2.0%–76.1%) among children suffered moderate/severe RV gastroenteritis. Two oral rotavirus vaccines marketed internationally, namely Rotarix® (GlaxoSmithKline Biologicals, the monovalent (RV1)) and RotaTeq® (Merck & Co. Inc., the pentavalent (RV5)) have completed the clinical test in China in 2012 and 2015 respectively, however, due to the concern of porcine circovirus (PCV) contamination with master seed, the licensure of Rotarix® was shelved, while RotaTeq® is most likely approved in the coming months. At the moment, two reassortant candidates were developed by China National Biologicals Group (CNBG). Of these, the hexavalent (bovine and human reassortant) that is composed of G1, G2, G3,

G4, G8 and G9 has passed phase I, and the phase II trial is ongoing. The trivalent (lamp and human reassortant) including G2, G3, G4 has completed phase III, and submitted NDA, a protection against severe diarrhea of >75% was demonstrated. With regard to the causality association between replicable vaccines and intussusception, an inactivated vaccine candidate based on a high replicable strain characterized as G1P[8] is being developed by Institute of Medical Biology, Chinese Academy of Medicine Science, and IND application was submitted in 2016. It is foreseeable that in the near future, adequate products can meet the demand of both EPI and catch-up immunization in China. In contrast, a feasible immunization policy as well as a financial mechanism suiting to China's national conditions is an urge challenge.