

comparable safety profile.

Table III: Sabin Inactivated Poliovirus Vaccine (sIPV)

Question necessary for recommendation development: Can Sabin Inactivated Poliovirus Vaccine (sIPV) be used interchangeably with Salk-based IPV (wIPV), in other words, is it equally immunogenic? What is the immunogenicity of sIPV compared to wIPV in immunocompetent children? Rating Adjustment to rating 8 RCTs1 No of studies/starting rating Limitation in study design None serious² 0 0 Inconsistency None serious Factors decreasing **Quality Assessment** 0 Indirectness None serious confidence 0 Imprecision None serious Publication bias None detected O 0 Strength of association Not applicable Factors increasing Not applicable 0 Dose-response confidence Mitigated bias and Not applicable 0 confounding Final numerical rating of quality of evidence 4 Evidence supports a high level of Summary of confidence that the true effect lies close Findings Statement on quality of evidence to that of the estimate of the effect on the health outcome. sIPV is shown to provide non-inferior Conclusion immunogenicity to wIPV and has a

Population: Immunocompetent children

Intervention: sIPV

Comparison: wIPV (conventional IPV)

Outcome : Immunogenicity for type 2 poliovirus

¹ Resik et al (2014) studied sIPV, aluminum adjuvanted dose sIPV and wIPV in adult males. No serious adverse events were reported attributed to trial interventions after 6 months. One month after vaccination, all vaccination groups experienced boosted immune responses against poliovirus types 1-3 between 90% and 100%. Verdijk et al (2013) also studied sIPV, aluminum adjuvanted dose sIPV and wIPV in adult males for safety and immunogenicity. Sabin-IPV and Sabin-IPV adjuvanted with aluminum hydroxide administered as a booster dose were equally immunogenic and safe as conventional IPV. Cramer et al (2020) conducted a phase 2/3 study that demonstrated optimal efficacy in a low-dose sIPV schedule and manufacturing lot consistency. sIPV was as safe and immunogenic as wIPV. Capeding et al (2021) showed the seroconversion rates for Sabin and wild strains of the 3 serotypes after the 3-dose primary series were 95.8% to 99.2% in the lot-combined sIPV group and 94.8% to 100% in the wIPV group, proving the noninferiority of sIPV compared to wIPV. Liao et al (2016) administered sIPV or wIPV (1:1 randomization) to infants aged 60-90 days. Seroconversion rates for SIPV recipients were 100%, 94.9%, and 99.0% (types I, II, and III, respectively) and 94.7%, 91.3%, and 97.9% for wIPV. This shows non-inferiority of sIPV. Sun et al (2017) demonstrated that sIPV vaccine can induce protective antibodies against currently circulating and reference wild poliovirus strains and most vaccine-derived poliovirus strains, with rare exceptions. Hu et al (2019) onducted a phase 3 trial showing sIPV with an immunogenicity profile noninferior to that of the conventional IPV and had a good safety profile in healthy infants. Jiang et al (2019) conducted a phase IV study and concluded that sIPV exhibits good lot-to-lot consistency and safety in large-scale populations; thus, it is qualified to serve as one of the vaccines for use in eradicating all wild and vaccine-derived polioviruses worldwide in the near future.

² The study by Cramer et al (2020) was not powered for statistical comparisons, so all comparisons were intended to be descriptive. Resik et al (2014) did not report status of participant/personnel blinding. This was not seen as a limitation that leads to downgrading of the evidence.

References

- 1. Resik S et al. Reactogenicity and immunogenicity of inactivated poliovirus vaccine produced from Sabin strains: A phase I trial in healthy adults in Cuba. Vaccine. 2014; 32: 5399-5404.
- 2. Verdijk P et al. Safety and immunogenicity of inactivated poliovirus vaccine based on Sabin strains with and without aluminum hydroxide: a phase I trial in healthy adults. Vaccine. 2013; 31(47): 5531-5536.
- 3. Cramer JP et al. Safety and immunogenicity of experimental stand-alone trivalent, inactivated Sabin-strain polio vaccine formulations in healthy infants: A randomized, observer-blind, controlled phase 1/2 trial. Vaccine. 2020; 38(33):5313-5323.
- 4. Capeding MR et al. Safety and immunogenicity of a new inactivated polio vaccine made from Sabin strains: a randomized, double-blind, active-controlled, phase 2/3 seamless study. J Infect Dis. 2021: 1-11.
- 5. Liao G et al. Phase 3 Trial of a Sabin Strain-Based Inactivated Poliovirus Vaccine. J Infect Dis. 2016; 214: 1728-1734.
- 6. Sun M et al. Immune Serum from Sabin Inactivated Poliovirus Vaccine Immunization Neutralizes Multiple Individual Wild and Vaccine-Derived Poliovirus. Clinical Infectious Diseases. 2017; 64(10): 1317-1325.
- 7. Hu Y et al. Immunogenicity and Safety of a Sabin Strain-Based Inactivated Polio Vaccine: A Phase 3 Clinical Trial. J Infect Dis. 2019; 220(10): 1551-1557.
- 8. Jiang R et al. Immunogenicity and safety of the inactivated poliomyelitis vaccine made from Sabin strains in a phase IV clinical trial for the vaccination of a large population. Vaccine. 2021; 39(9): 1463-1471.